

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit 1638

In re

Patent Application of

Paul Sun, et. al.

Application No. 09/773,976

Confirmation No. 6280

Filed: January 31, 2001

Examiner: Fox, David T.

"ALFALFA HYBRIDS HAVING AT LEAST 75%

HYBRIDITY"

I, Mary A. Hietpas, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on the date of my signature.

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APPEAL BRIEF UNDER 37 CFR 1.192

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Sir:

Concerning the above-referenced patent application, the Appellants have appealed from the final rejection of claims 1-9, dated June 2, 2003. Appellants are submitting this Appeal Brief in triplicate in support of their appeal. A check in the amount of \$165 is submitted in payment of the official filing fee. A request for a two-month extension of time and a check in the amount of \$210 is also being submitted herewith, extending the deadline for filing the Appeal Brief to January 2, 2004.

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REAL PARTY IN INTEREST

The real party-in-interest is Dairyland Seed Co., Inc., to which the inventors have assigned their entire right, title and interest in and to the invention in assignment recorded May 14, 2001.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 1-9 are pending. Claim 10 is cancelled. Claims 1-9 stand rejected and appealed.

STATUS OF AMENDMENTS

In response to the first Office Action on the merits, an Amendment was filed on September 10, 2002, amending the specification, canceling claim 10 and amending claims 1, 2, 5, 7, 8 and 9. In an Office Communication mailed January 28, 2003, Appellants were informed that this Amendment was not entered because a marked-up version of the amendments to the specification was not submitted. Appellants resubmitted the Amendment on February 27, 2003, again amending the specification, canceling claim 10 and amending claims 1, 2, 5, 7, 8 and 9 and including marked up versions of the specification and claims. This Amendment was entered.

In response to the final Office Action, Appellants submitted an Amendment on September 2, 2003, in which claims 2 and 9 were amended. In an Advisory Action mailed October 30, 2003, Appellants were advised that the Amendment was entered.

¹ Claim 10 and an accompanying description of the claim as "cancelled" was inadvertently omitted from the previous Listing of Claims submitted with Applicant's Response of September 2, 2003.

SUMMARY OF THE INVENTION

The presently claimed invention is directed to a novel *Medicago sativa* hybrid cultivar designated DS9705Hyb. The novel culitvar exhibits agronomically desirable traits, including high forage yields, high seed yields, winter hardiness and improved disease resistance, among other beneficial characteristics. Additionally, DS9705Hyb hybrid plants exhibit improved uniformity in characteristics than is typically observed in hybrid breeding programs. In one aspect, the invention provides seeds of the DS9705Hyb hybrid, which are deposited under the Budapest Treaty with the American Type Culture Collection (Accession Number PTA-2759). The invention also provides alfalfa plants grown directly from the seeds deposited under ATCC Accession Number PTA-2759. Plants grown from a vegetative cutting, callus or tissue culture taken from a plant grown directly from the deposited seeds are also encompassed by the invention, as well as pollen and ovules from the plants.

The presently claimed invention is also directed to a novel method of producing alfalfa seeds having at least 75% hybridity, i.e., 75% of plants contain genetic traits of both parental lines. The claimed method includes steps of: crossing cytoplasmic male sterile alfalfa plants with maintainer alfalfa plants to produce cytoplasmic male sterile hybrid plants; selectively harvesting seed from the cytoplasmic male sterile plants; crossing male sterile hybrid plants by male fertile alfalfa plants by open pollination by growing the seed from male sterile hybrid plants with seed from at least one line of male fertile alfalfa plants, the male sterile and male fertile seed planted at a ratio of about four male sterile seeds to one male fertile seed; and non-selectively recovering seeds from the pollinated alfalfa plants. The method of the invention differs from traditional hybrid breeding methods in that about a 4:1 planting ratio of male sterile and male fertile seed is used to yield optimum results. A further optional step in the method

includes determining the hybridity of the progeny of the crossing. Optionally, hybridity is determined using morphological or genetic markers. If genetic markers are used to determine hybridity, the analysis may be done using amplified fragment length polymorphism ("AFLP") techniques. In a preferred embodiment, the method of the invention yields at least 80% of the average seed yield of the male fertile parental line.

STATEMENT OF THE ISSUES

The issues presented in this appeal are as follows:

- (1) Whether claims 1-9 are unpatentable under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention.
- (2) Whether claims 1-4 are unpatentable under 35 USC §102(b) as anticipated by Northrup et al. (Seed Scoop Vol. 19, No. 4. p. 6 (1972)).
- (3) Whether claims 2-4 are unpatentable under 35 USC §102(b) as anticipated by or, in the alternative, under 35 USC §103(a) as obvious over each of Northrup et al. and Thompson et al. (Crop Science Vol. 14, p. 609 (1974)).
- (4) Whether claims 5, 6 and 9 are unpatentable under 35 USC §103(a) as obvious over Sun et al. (U.S. Patent No. 4,045,912).
- (5) Whether claims 5-7 are unpatentable under 35 USC §103(a) as obvious over Sun et al. in view of Viands et al. (Ch. 30: Alfalfa and Alfalfa Improvement, Agronomy Monograph No. 29, Crop Sci. Soc. of America, pp. 931-960 (1988)).

(6) Whether claims 5 and 8 are unpatentable under 35 USC §103(a) as obvious over Sun et al. in view of Rotili et al. (Plant Science Vol. 32, No. 6, pp. 15-17 (1995) and further in view of Vos et al. (Nucleic Acid Research Vol. 23, No. 21, pp. 4407-4414 (1995).

GROUPING OF CLAIMS

For purposes of the substantive rejections under 35 USC §§ 112, 102 and 103, the rejected claims do not stand or fall together, and the following groups of claims are separately patentable:

Group I: Claim 1

Group II: Claims 2-4

Group III: Claims 5 and 9

Group IV: Claims 6-8

ARGUMENT

Introduction

It is respectfully asserted that the Examiner's misunderstanding of the invention, and the Examiner's repeated mischaracterization of the invention as a "synthetic variety" (when the evidence presented in the specification and prosecution history clearly and convincingly demonstrates that the invention is a hybrid variety) has led the Examiner to maintain the claim rejections in the present application. Appellants respectfully assert that consideration of the evidence of record and the arguments presented herein will lead the Board to reverse each of the rejections in the present case.

5

Rejection of Claims 1-9 Under 35 U.S.C. § 112, First Paragraph

The Examiner has maintained the rejection of the claims of Groups I-IV, asserting that claims 1-9 are unpatentable under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining what constitutes "undue experimentation" are set forth in *In re Wands*, 858 F.2d 731, 737; 8 USPQ 2d 1400 at 1404 (Fed. Cir. 1988): (1) the breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) level of one of ordinary skill; (5) level of predictability; (6) amount of direction or guidance provided; (6) existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure. For the reasons that follow, Appellants respectfully assert that the claimed invention may be practiced by the skilled artisan without undue experimentation.

Group I

With respect to Group I (claim 1), directed to a seed deposited as ATCC Accession

Number PTA-2759, the gravamen of the Examiner's position appears to be that the claim should
be broadly interpreted to cover any alfalfa seed "derived with the synthetic variety Thor." The

Examiner then asserts, in light of this broad interpretation, that Appellants have not provided
enabling disclosure sufficient to represent a synthetic variety.

Appellants respectfully assert that the Examiner's overbroad claim interpretation is not warranted in light of the specification and evidence of record. Appellants further assert that the claimed invention, when properly interpreted, is fully supported by an enabling disclosure.

The Examiner asserts that the claimed invention is indistinguishable from synthetic variety. Thor because the specification includes a description of Thor in the parental lineage.

The Examiner is not correct. As taught by Fehr et al., cited by the Examiner, a hybrid is defined as "the first generation progeny from a cross involving inbred lines." Fehr et al., Principals of Cultivar Development, Ch. 33, p. 244 (1987). An inbred line is described as:

a pure line, or nearly homozygous line, usually developed by inbreeding. The source of inbreds may be an open-pollinated variety; a single-, three-way or double-cross hybrid; a synthetic variety; or a population improved through recurrent selection.

Id. (emphasis added). Thus, as is known in the art, the use of a synthetic variety for further hybrid development is <u>not</u> understood to render the derived hybrid variety a synthetic *per se* as the Examiner asserts.

In addition, the above definitions describing a hybrid closely track the present specification's description of the development of the claimed hybrid, further evidencing that one of skill in the art would understand the claimed invention to be a hybrid alfalfa, and not a synthetic. Compare Fehr et al., illustration at p. 244 with specification page 4, line 29-page 5, line 12. Based on the description in the specification, one skilled in the art would appreciate that the claimed invention was made using selected parental components, rather than a commercial variety. For example, the description of the method of the invention at page 4, line 29-page 5, line 12 (reproduced below with emphasis added), clearly indicates that the method employs selected lines or clones of alfalfa:

Briefly, the method of the invention is performed as follows:

1. Alfalfa plants with desirable agronomic traits are selected. Male sterile A line plants are selected from male sterile ("female") populations, maintainer B line plants are selected from maintainer populations, and pollenizer C line plants are selected from restorer populations, or from clonal or synthetic populations.

- 2. The selected A and B lines are grown from cuttings or seed and cross pollinated using bees to produce hybrid male sterile breeder and foundation seeds. Seeds are harvested from cytoplasmic male sterile plants only.
- 3. Selected pollenizer plants are selfed or interpollinated by bees to produce breeder and foundation pollenizer seeds and the seed is harvested in bulk.
- 4. For large scale commercial production of hybrids, male sterile seeds and pollenizer seeds are planted at a ratio of male sterile seeds and male fertile (pollenizer) seeds of about 4:1, and the plants grown therefrom are pollinated.
- 5. Seeds are harvested in bulk from the plants grown from the seed of step 4, above.
- 6. Optionally, the percentage hybridity can be determined using either genetic or morphological markers.

The Examiner has also broadly interpreted the names DS9705Hyb, A833, B209, DS9761, and C580 as "synthetic varieties." Contrary to the Examiner's interpretation of parental components A833, B209, Thor, DS9671, and C580 as being synthetic <u>varieties</u>, Appellants have described the plants identified by these terms as being alfalfa plant <u>lines</u> at least at page 6, lines 1-4 (emphasis added):

In the examples below, male sterile line A833, maintainer line B209, and **pollenizer lines** Thor, DS9671, and C580 were used. One of ordinary skill in the art will appreciate that any suitable male sterile line, maintainer line, and pollenizer line could be successfully employed in the practice of the method of the invention.

Further, throughout the specification, the Appellants made clear that the terms Thor, DS9671, C580, and B209 were intended to refer to using selected clones, or the S1 progeny of selected clones, rather than commercial varieties (e.g., page 7, lines 10-12). As inventor Dr. Sun explained in his Declaration at page 2, paragraph 7, another copy of which is attached hereto as Exhibit A, a pollenizer <u>line</u> is understood by one of skill in the art to mean "a group of individuals from a common ancestry, which is narrower than a strain or variety." One of ordinary

skill in the art would understand that a plant clone is a plant or group of plants originated by vegetative propagation from a single plant.

The specification clearly distinguishes between synthetic varieties (Vernal and Saranac), hybrids (A833 xB209, A833 xB209 (S1) and DS9750Hyb) and selected clones (Thor, DS9761, and C580). For example, on pages 7-10 of the specification, the Examples detail studies in which characteristics of hybrids produced according to the invention were compared with synthetic varieties (Vernal and Saranac) and selected clones (Thor, DS9761, and C580). Characteristics of hybrids of crosses between a male sterile line (A833) and a maintainer line (B209), and hybrid DS9705Hyb, the components of which include a cytoplasmic male sterile hybrid plant (A833xB209), and selected pollenizer lines were also compared with synthetic varieties on pages 11-24 (Tables 1-23)².

Importantly, not only do the Examples and Tables distinguish between synthetics, hybrid components and hybrids, but they also provide detailed guidance to the skilled artisan with respect to the parental components of the claimed hybrid seed and plant, which the Examiner has maintained is lacking. Contrary to the Examiner's position, the Examples and Tables provide the skilled artisan with information regarding the parental lines' plant size (in relation to commercial varieties Vernal and Saranac), winter survival rates, spring vigor assessments, flowering dates, flower color, pollen production index, disease resistance, forage yield and seed yield.

Moreover, precedent of the Board has established that with respect to a hybrid plant, a deposit of seed enables claims to the seed. In Appeal No. 92-0393 from Art Unit 1804, 27

² In the Advisory Action, the Examiner asserts that the Tables on pp. 15-17 and 21-22 indicate that DS9705Hyb is a synthetic. This is inaccurate. The Tables inadvertently included "Syn Gen" as a column heading, but should instead read simply "Gen." For the reasons asserted herein, however, one of skill in the art would appreciate that the listed lines and hybrids are not synthetics, despite the typographic error in the column headings.

USPQ2d 1492 (BPAI 1992)³, a case with facts strikingly similar to this one, the claims were directed to a method of producing a hybrid soybean plant, the hybrid soybean plant, the seed which produced the hybrid soybean plant and seed produced by the hybrid soybean plant. The Examiner rejected the claims under 35 USC § 112, first paragraph. It was the Examiner's position that because the specification omitted information concerning the breeding process, the selection pressures for disease resistance, the methods of measuring and testing resistance, etc., one of ordinary skill in the art could not independently develop the claimed hybrid. The Appellant offered to deposit the seeds with the ATCC. The Board held that the availability of the seeds through the ATCC depository enabled one of skill in the art to grow a plant and produce additional seeds therefrom. The Board stated:

An exacting description relating to how to select for the desired plant could only detail an experimental screening program which would not necessarily result in the exact same plant being obtained, but, rather, would result in one which, though different, would have virtually the same characteristics. We are in agreement with the appellant that upon deposit of the seeds in the ATCC, the specification satisfies the enablement and best mode requirements of 35 USC § 112.

In light of the description of the characteristics of the parental lines in the present case and the ATCC deposit of the claimed hybrid seeds, Appellant respectfully request that the Board reverse the rejection of claim 1 under 35 USC § 112.

Group II

Claims 2-4 (Group II) are directed to plants grown directly from the seed deposited as ATCC Accession Number PTA-2759, or plants grown indirectly (i.e., clonally or from

³ For the convenience of the members of the Board, a copy of the published decision is attached as Exhibit B.

vegetative cuttings, etc.) from the seed deposited as ATCC Accession Number PTA-2759, and pollen and ovules produced from the plants grown directly from the deposited seed.

For the many of same reasons that the claim to the deposited seed is enabled by the specification in light of the ATCC deposit, *a fortiori*, claims to a plant grown therefrom, or grown indirectly from a plant grown therefrom, are enabled as well. It is elementary that a party in possession of the claimed deposited seeds would be able to make and use the claimed hybrid plants by simply planting and cultivating the seeds. Once in possession of the plants, that party would also be able to obtain pollen (claim 3) and ovules (claim 4), as well as produce additional plants via a vegetative cutting, callus or tissue culture. As stated by the Board, "there is no question that one having seeds available through the ATCC depository would be enabled to grow a plant and produce additional seeds therefrom." Appeal No. 92-0393 from Art Unit 1804, 27 USPQ2d 1492 (BPAI 1992).

In the Advisory Action, however, the Examiner states that claim 2 "reads on somaclonal variants, since it has been amended to encompass plants grown from tissue or callus, which are known to generate somaclonal variants which do not have the same genotype or phenotype as the plants from which they are obtained." The Examiner ignores the fact that at least some culture-derived plants are necessarily genetically the same or nearly the same as the plant from which the cultured cells were derived. Screening for the desired plants and eliminating somaclonal variants are tasks well within the skill in the art. Thus, despite the biological possibility of somaclonal variants, the skilled artisan is nevertheless enabled to make and use the claimed hybrid plant without undue experimentation.

Group III

Claims 5 and 9 (Group III) are directed to a method of producing alfalfa seeds having at least 75% hybridity, and in one claimed embodiment, a method wherein the average seed yield is at least 80% of the average seed yield obtainable by selfing the male fertile plants obtained in the second crossing step recited in the method. With respect to these claims, the Examiner asserted that methods of producing alfalfa seeds having 75% hybridity are subject to biological constraints such that the open pollination planting ratio claimed (i.e., 4:1) would not ensure a hybridity of at least 75% or a yield of 80% "in consideration of the totality of all alfalfa plants of differing pollen fertility as broadly claimed." Office Action dated 3-15-2002, pp. 8-9 (emphasis added). Even assuming arguendo that the Examiner's proposition (for which no authority whatsoever is cited) is correct, in light of the high level of skill in the art and the guidance provided in the specification, Appellants assert that performing the claimed method is nevertheless enabled.

The necessary corollary to the Examiner's assertion is that to be enabled, the claims to methods of producing alfalfa plants must "ensure" 75% hybridity and 80% yield. This is not the standard of 35 USC § 112, first paragraph. Some experimentation by the skilled artisan is permissible, as long as it is not "undue." Factors to be considered in determining what constitutes "undue experimentation" are: (1) the breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) level of one of ordinary skill; (5) level of predictability; (6) amount of direction or guidance provided; (6) existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In* re Wands, 858 F.2d 731, 737; 8 USPQ 2d 1400 at 1404 (Fed. Cir. 1988). Here, at least the state

of the art, the level of ordinary skill in the art, and the amount of guidance and working examples provided in the specification weigh in favor of enablement of the claims of Group III.

With respect to the state of the art, the Examiner has recognized⁴ that Sun et al., U.S. Patent No. 4,045,912, incorporated by reference in the present specification, teaches a process of producing hybrid alfalfa seeds which comprises crossing by controlled pollination cytoplasmic male sterile alfalfa plant with maintainer line alfalfa plants to provide hybrid male sterile alfalfa seeds, selectively recovering the hybrid seeds, crossing by random pollination, plants derived from the hybrid seeds randomly mixed with male fertile plants in ratio of 1:1 to 3:1 and non-selectively recovering the seeds from the crossing. Col. 11, lines 38-54. Thus, the state of the art at the time of filing the present invention, while failing to teach or suggest all required elements of the present claims, had nonetheless advanced regarding the production of hybrid alfalfa seed.

The level of skill in the art of plant breeding and development of plant varieties is high.

Finally, as noted above, the present specification provides detailed guidance regarding the method of the invention and the development of an example, DS9705Hyb, produced according the method of the invention, including measurements of its properties and comparisons to properties of parental components and synthetic varieties.

Therefore, Appellants respectfully assert that the invention claimed in Group III is wholly enabled in light of the guidance and examples provided in the specification, the high level of skill in the art, and the state of the prior art and therefore request that the Board reverse the rejection.

⁴ See rejection under 35 USC § 103/102(b) over Sun et al.

Group IV

Claims 6-8 (Group IV) are directed to methods of producing alfalfa seeds having at least 75% hybridity, further including a step of determining the hybridity of the progeny of the crossing.

With respect to Group IV, the Examiner asserts that Appellants have failed to provide sufficient guidance as to how one would go about assessing the percent hybridity. Appellants provided an example of one method by which one would go about determining the percent hybridity using molecular markers. Determining the percent hybridity is routinely used in plant breeding and is well within the ability of one of ordinary skill in the art. Appellants note the Examiner has acknowledged as much with respect to at least morphological markers in the 3-15-2002 Office Action at page 15, third paragraph: "Sun et al. teach in Table II the determination of the hybridity of the open pollination step."

With respect to determining the percent hybridity using molecular markers, the specification provides ample guidance to the skilled artisan, at least in the form of a working example. At page 10 of the specification, Appellants describe assessing the hybridity of the hybrid DS9705Hyb by selfing plants of the parental lines B209, DS9671, C580, and Thor to generate pure S1 seed, and isolating DNA from plants grown from the S1 seed for subsequent analysis. The Example at page 10 (and sequence listing for SEQ ID NOS: 1-4) further provides sequences for four primers used to determine the hybridity of plants grown from DS9750Hyb seed.

Despite the Examiner's unsupported argument to the contrary (see, e.g., Advisory Action at page 2), one of skill in the art would appreciate that in order to evaluate hybridity using molecular markers, one compares the characteristics of plants grown from a crossing with those

of the parental components. The specification, at least by way of example, provides additional guidance with respect to a method of determining hybridity that is routinely practiced by skilled artisans without undue experimentation.

Therefore, Appellants respectfully assert that the claims of Group IV, in light of the level of skill in the art and guidance presented in the specification, are fully enabled.

Rejection of Claims 1-4 Under 35 U.S.C. § 102(b)/ §103

Groups I and II

The Examiner has maintained the rejection of claims 1-4 as anticipated over Northrup et al. Claims 2-4 stand rejected as anticipated by, or in the alternative, as obvious over Northrup et al. and Thompson et al.

Northrup et al. teach that Thor is a synthetic variety. Thompson et al. teach the development of an unrelated synthetic variety named "Syn C."

The Examiner asserts that seeds of Thor are inherently included in the deposited seed. Thus, the rejections stem from the Examiner's continued insistence that the claimed invention is developed using the synthetic variety Thor rather than a selected line of Thor, a proposition that Appellants continue to strenuously dispute, as discussed above. As noted, the Examiner has interpreted the names A833, B209, C580, DS9761 and Thor as being designations for synthetic populations or varieties, despite evidence to the contrary presented during prosecution and in the Declaration of Dr. Paul Sun at paragraph 9:

As one skilled in the art, it is my opinion that the application clearly describes that the seed identified by Accession Number PTA-2759 was obtained by crossing cytoplasmic male sterile hybrid plants with select clones or plant lines, rather than with a synthetic variety.

As Appellants have described in the specification and explained above, the pollenizer plants used as parental components to produce the seed of claim 1 were selected on the basis of desirable agronomic characteristics and selfed or interpollinated to obtain breeder and foundation seed. These select clones are distinct from grown from synthetic varietal seed. A833 is a cytoplasmic male sterile line and B209 is a maintainer line, each of which was selected as described in the specification. Appellants respectfully submit that none of the plants obtainable by growing the seed of claim 1 is identical to plants grown from synthetic varietal seed of Thor.

The Examiner's citation of *In re Thorpe* regarding product-by-process claims is inapposite. The Application does not include product-by-process claims. Moreover, as asserted above, the "product," which Appellants take to mean the claimed seeds of Group I and claimed plants of Group II, are not identical in any respect to the seeds or plants taught in either of Northrup et al. or Thompson et al., inherently or otherwise.

Rejections Under 35 U.S.C. §103

Groups III and IV

The Examiner has maintained the rejection of claims 5-6 and 9 as obvious over Sun et al. Claims 5-7 stand rejected as obvious over Sun et al. in view of Viands et al. Claims 5 and 8 stand rejected as obvious over Sun et al. in view of Rotili et al., in further view of Vos et al.

The Examiner asserts that Sun et al. (US Patent No. 4,045,912) teaches a method of making alfalfa seed with 76.3 or 85% hybridity using a ratio of 3:1 male sterile to male fertile seed. The Examiner also asserts that Sun et al. teach increases in the percent hybridity obtained with increasing ratios of male sterile to male fertile alfalfa plants. The Examiner concludes that it would have been "an obvious design choice by one of ordinary skill in the art to utilize the

method for producing a synthetic variety taught by Sun et al. and modify the ratio of pollenizers from the 3:1 ratio taught by Sun et al., ... to design a method with a 4:1 ratio which could make alfalfa plant with at least an 85% increase in seed yield as broadly claimed."

Appellants respectfully submit that the Examiner has failed to establish a prima facie case of obviousness, which requires: (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) a reasonable expectation of success; and (3) the art reference or combination of references must teach all of the claim limitations (MPEP 2142). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (MPEP 2143).

Appellants assert that: (1) all of the claim limitations are not taught or suggested by the references; (2) there is no suggestion to modify or combine the cited art to arrive at the claimed invention: (3) there is no reasonable expectation of success; and (4) the primary reference actually teaches away from the claimed invention, as is detailed below.

(1) Claim Limitations Not Taught or Suggested

As the Examiner has acknowledged, Sun et al. does not teach or suggest practicing a method of producing alfalfa seed having at least 75% hybridity comprising crossing male sterile hybrid alfalfa by male fertile alfalfa plants planted in a ratio of about 4:1, as required by independent claim 5 and its dependent claims 6-9. None of the secondary references teach a planting ratio of 4:1.

(2) No Suggestion To Modify or Combine Cited Art

Sun et al. provides no motivation to increase the planting ratio. Sun et al. teaches that maximum seed yield is obtained by planting male sterile and male fertile plants in a ratio of 1:1 to 3:1, and that these ratios <u>must</u> be used. Col. 3, lines 13-16 (emphasis added). The Examiner maintains however, that a select portion of Table II, i.e., Replicate II, teaches a general trend of increased hybridity from increasing planting ratios. What the Examiner ignores, however, is that Table II, in the column titled "Average of 2 Replicates," (which is more appropriately used to interpret the data presented) further demonstrates that decreased seed yield also results from increasing planting ratios. For example, in the upper group of data in the "wt./pl." column, as the ratio increases from 1:1 to 2:1 to 3:1, the seed yield decreases from 59.9 to 46.6 to 38.9, respectively. Thus, one of skill in the art would understand from both Table II and the text of Sun et al. that in order to optimize both seed yield and hybridity, the planting ratio must remain within the stated range of 3:1 to 1:1. Therefore, Sun et al. provides no suggestion to modify the ratio to arrive at the claimed invention, requiring a planting ratio of 4:1. None of the secondary references cure this deficiency.

(3) No Expectation of Success

Similarly, Sun et al. provides no reasonable expectation of success in a modified planting ratio. As noted above, the data presented in Table II suggest that the achieving the optimum balance between seed yield and hybridity requires that the planting ratio remain within the stated range of 1:1 to 3:1. Thus, one of skill in the art would not expect success in the utilization of any increased planting ratio, much less the claimed ratio of 4:1.

(4) Clear Teaching Away From Claimed Invention

Finally, Sun et al. <u>teaches away</u> from increasing the ratio of male sterile to male fertile plants to any ratio greater than 3:1. Sun et al. teaches that male sterile alfalfa have reduced seed yield relative to male fertile alfalfa (column 1, lines 34-37), and that in order to obtain maximum seed production, "the ratio of male sterile to male fertile alfalfa plants <u>must</u> be in the range of 1:1 to 3:1" (column 3, lines 13-17, emphasis added). Thus, in the face of this teaching, one of skill in the art would be discouraged from altering the ratios taught. Proceeding contrary to the accepted wisdom in the art is evidence of <u>non-obviousness</u>. MPEP 2145. None of Viands, Rotili or Vos cure the deficiencies of Sun et al. by teaching or suggesting the claimed ratio.

The Examiner further maintains that the Appellants have not demonstrated any advantage in using a planting ratio of 4:1 and that the increase in the planting ratio over that used in Sun et al. does not provide unexpected results. However, Appellants respectfully assert that it is the Office's initial burden to demonstrate *prima facie* obviousness, not Appellants' burden to demonstrate unexpected results in the first instance. MPEP 2142.

As demonstrated above, the Examiner has not established obviousness of the claimed invention over any of Sun et al., Viands et al., Rotili et al., Vos et al., or any combination thereof. Appellants are not therefore required to show unexpected results to establish non-obviousness of the presently claimed invention. To the contrary, because all claimed elements are not taught by the cited art, because there is no motivation to combine the cited art, because there is no expectation of success and because the primary reference clearly teaches away from the presently claimed invention, Appellants assert that the claims of Groups III and IV are not obvious over the cited art. Therefore, withdrawal of the rejections is respectfully requested.

Conclusion

In view of the foregoing, reversal of the final rejection of claims 1-9 and allowance of claims 1-9 are respectfully requested.

Respectfully submitted,

Billie Jean Smith Reg. No. 36,940

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(414) 271-6560

APPENDIX

LISTING OF CLAIMS

This Listing of Claims will replace all prior versions of claims in the application.

Claim 1 (Previously presented): A *Medicago sativa* or cultivated alfalfa seed deposited as ATCC Accession Number PTA-2759.

Claim 2 (Previously presented): A *Medicago sativa* hybrid or cultivated alfalfa plant that is grown directly from the seed deposited as ATCC Accession Number PTA-2759, or a plant grown from a vegetative cutting, callus or tissue culture obtained from a plant part grown from the seed deposited as ATCC Accession Number PTA-2759, or a clonal plant thereof.

Claim 3 (Original): Pollen from the plant of claim 2.

Claim 4 (Original): An ovule from the plant of claim 2.

Claim 5 (Previously presented): A method of producing alfalfa seeds having at least 75% hybridity comprising the steps of:

- (a) crossing by controlled pollination cytoplasmic male sterile alfalfa plants with maintainer line alfalfa plants to produce cytoplasmic male sterile hybrid plants;
- (b) selectively harvesting seed from the cytoplasmic male sterile hybrid plants of step(a);

(c) crossing male sterile hybrid alfalfa plants by male fertile alfalfa plants by allowing open pollination of plants grown from the seed of step (b) and seed from at least one line of male fertile alfalfa plants, the male sterile seed and male fertile seed planted at a ratio of about 4:1; and

(d) non-selectively recovering the seeds from the pollinated alfalfa plants of step (c).

Claim 6 (Original): The method of claim 5, further comprising the step of determining the hybridity of the progeny of the crossing.

Claim 7 (Previously presented): The method of claim 6, wherein the step of determining the hybridity of the progeny of the crossing is with a genetic or morphological marker.

Claim 8 (Previously presented): The method of claim 6, wherein the step of determining the hybridity is accomplished with amplified fragment length polymorphism analysis.

Claim 9 (Previously presented): The method of claim 5, wherein the average seed yield of step (d) is at least 80% of the average seed yield obtainable by selfing the male fertile plants of step (c).

Claim 10 (Cancelled)

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant(s): Sun, et al.

Docket No.:

87165/9051

Serial No.:

09/773,976

Group Art Unit:

Filing Date: January 31, 2001

Examiner:

Francis P. Moonan

Confirmation No.: 6280

Title:

ALFALFA HYBRIDS HAVING AT LEAST 75% HYBRIDITY

DECLARATION OF PAUL SUN UNDER 37 CFR § 1.132

Assistant Commissioner for Patents Washington, DC 20231

Sir:

I, Paul Sun, do hereby declare and state the following:

- I am a co-inventor of the subject matter of the above-cited application. 1.
- I am employed as Vice President of Research at Dairyland Seed, Clinton, WI, where I 2. have worked since since 1981.
- I received my Ph.D. in Plant Breeding and Genetics from the University of 3. Wisconsin-Madison in 1969. This Declaration is accompanied by my curriculam vitae, attached as Appendix A.
- I have reviewed the Office Action dated March 15, 2002 (hereinafter, "the Office 4. Action") and the references cited therein.
- Claims 1-10 of the present invention are rejected under 35 U.S.C. 112, first paragraph 5. as not being enabled by Applicants' disclosure. The Examiner stated that claim 1 is drawn to any Medicago sativa or cultivated alfalfa seed derived with the synthetic variety Thor, based on Applicants' description at page 2, lines 6-10, which the Examiner characterized as "describing to one of skill in the art a plant made with a series of alfalfa plants with arbitrary names and a population of genetically segregating alfalfa plants comprising the synthetic variety Thor." Based on his assessment of what one of skill in the art would understand from the disclosure, the Examiner broadly interpreted the names DS9705Hyb, A833, B209, DS9761, and C580 as "synthetic varieties".

- 6. The alfalfa seed deposited with the ATCC on December 4, 2000 and identified by Accession Number PTA-2759 was made by crossing a selected cytoplasmic male sterile alfalfa plant (A833) with a selected maintainer line (B209) by controlled pollination and selectively harvesting seed from the cytoplasmic male sterile plant to produce cytoplasmic male sterile hybrid seed (A833xB209). Plants grown from seed of A833xB209 cytoplasmic male sterile hybrid were crossed by open pollination with plants grown from seed from selected alfalfa male fertile clones which are designated Thor, DS9671 and C580. These selected clones were selected on the basis of agronomically desired properties such as: forage yield, forage quality, persistence, disease, insect and nematode resistance.
- 7. Applicants referred to the specific parental components ((A833xB209), Thor, DS9671, and C580) of the hybrid seed identified by Accession Number PTA-2759 as selected clones or plant lines. One of ordinary skill in the art would understand that a plant clone is a group of plants originated by vegetative propagation from a single plant, and that a plant line is a group of individuals from a common ancestry, which is narrower than a strain or variety.
- I participated in the preparation of the patent application, and reviewed and approved the application that was filed with the United States Patent and Trademark Office on January 31, 2001. At the time the application was filed, it was my opinion that the application clearly described the method by which the seed deposited as identified by Accession Number PTA-2759 was obtained, specifically, by crossing cytoplasmic male sterile hybrid plants with select clones or plant lines, rather than with a synthetic variety.
- 9. I have reviewed the application in light of the Examiner's rejection of the claims on the basis of lack of enablement. As one skilled in the art, it is my opinion that the application clearly describes that the seed identified identified by Accession Number PTA-2759 was obtained by crossing cytoplasmic male sterile hybrid plants with select clones or plant lines, rather than with a synthetic variety.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dared: 9/6, 200 2.

Curriculum Vitae of Paul Sun

Education: 1957 B.S. Taiwan Agriculture College

1967: M.S. University of Wisconsin

1969: PH.D University of Wisconsin (Agronomy Dept)

Dissertation Title: Inheritance of Kernel Weight of six spring wheat crosses

Work Experience:

1969-1975: Alfalfa Breeder

Teweles Seed Company Clinton, WI 53525

Applied the concept of general combining ability and convergence of germplasm to alfalfa breeding and developed Magnum alfalfa which made 10% genetic gain in compare check variety Vernal in 1976.

1976-1980: Soybean Breeder

Pfizer Genetics Beaman, IA

Developed 5 commercially useful soybean varieties: CX155, CX276, CS290, CX297, CX380.

1981-2002: Research Director

Dairyland Seed Co., Inc. Clinton, WI 53525

Work on Hybrid Alfalfa, soybeans and Hybrid Com. In 1985, developed DSR317 soybean variety which made 5% genetic gain compared to the best mid 3 maturity soybean. DSR317 was on the market for 10 years. There are about 7 million bags of DSR317 and sister lines that were grown by farmers.

Patentee:

U.S. Patent No. 4,045,912

Issue Date: September 6, 1977

Title: PRODUCTION OF ALFALFA SEEDS

U.S. Patent No. 5,724,767 Issue Date: March 10, 1998

Title: ALFALFA PRODUCTS AND METHOD FOR PRODUCING

ALFALFA PRODUCTS FOR A SEQUENTIAL SYSTEM

U.S. Patent No. 6,051,759 Issue Date: April 18, 2000

Title: ALFALFA PRODUCTS AND METHOD FOR PRODUCING

ALFALFA PRODUCTS FOR A SEQUENTIAL

HARVESTING SYSTEM

U.S. Patent No. 6,359,199 Issue Date: March 18, 2002

Title: ALFALFA PRODUCTS AND METHOD FOR PRODUCING

ALFALFA PRODUCTS FOR A SEQUENTIAL

HARVESTING SYSTEM

Advisor:

1993 Sent by the United Nations to China for corn breeding advisor.

Visited five research stations, giving 12 lectures on corn breeding.

Publications: Inheritance of Kernel weight for six spring wheat crosses: Crop Sciences, 1971.

Co author on the Chapter of Pollination Control, Mechanical and Sterility of Agronomy NO. 29, Alfalfa and Alfalfa Improvement, Edited by A.A. Hanson,

D. K. Barnes and R.R. Hill, Jr., ASA, CSSA and SA, 1988.

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LEXSEE 1992 PAT APP LEXIS 35

Ex parte * * *

Appeal No. 92-0393 from Art Unit 1804.

Application for Patent Novel Soybean Variety * * *

Board of Patent Appeals and Interferences

1992 Pat. App. LEXIS 35; 27 U.S.P.Q.2D (BNA) 1492

September 28, 1992, Decided

[*1]

Before Goldstein, Goolkasian, McCandlish, Lynch and J. Smith, Examiners-in-Chief.

COUNSEL:

* * * et al. for appellant.

Supervisory Patent Examiner - Elizabeth C. Weimar

Examiner - P. Rhodes

OPINIONBY: GOOLKASIAN

OPINION:

Goolkasian, Examiner-in-Chief.

This is an appeal from the examiner's final rejection of claims 5 through 8, which are all the claims remaining in the application.

Claims 5 through 8 read as follows:

- 5. A method of producing * * * comprising self-pollinating an * * * soybean plant.
- 6. A soybean plant designated * * *
- 7. Seed, which upon germination produces the plant of claim 6.
- 8. Seed produced by the plant of claim 6.

The references relied on by the examiner are:

Russell, *Studies In The Agricultural And Food Sciences*, "Plant Breeding for Pest and Disease Resistance," Butterworths Press, 1978, pages 36-41.

SNB 112 Germplasm Resources Information Network release date of cultivar Pella 1979.

Keeling, *Plant Disease*, "A New Physiologic Rase of *Phytophthora megasperma* f. sp. *glycinea*," Vol. 68, No. 7, 1984, pages 626-627.

Athow, World Soybean Research Conference III, "Phytophithora Root Rot Of Soybean," Westview Press, 1985, pages 575-581.

PI 88447 Germplasm Resources [*2] Information Network, date available from USDA-ARS soybean collection 1986.

This invention concerns a novel variety of soybean plant, seeds produced therefrom, and a method of producing the seeds by self-pollinating the soybean plant. The novel variety, named * * *, was developed by appellant and is a cross between a commercial soybean known as * * * and a known variety available from Iowa State University and identified in the specification as 'Pella.'

Appellant seeks utility patent protection under 35 U.S.C. § 101. n1 Appellant's assignee, a seed producer, considers utility patent protection more desirable than protection under the Plant Variety Protection Act (PVP) because the PVP has a loophole therein known as the "farmer's exemption" which allows farmers to save and sell seeds in competition with the developer of the novel variety.

n1 The patentability of plants and seeds under 35 U.S.C. § 101 has been confirmed by this Board in Exparte Hibberd, 227 USPQ 443 (BPAI 1985).

Appellant's specification does not follow the standard format set forth in section 608.01(a) of the Manual of Patent Examining Procedure (M.P.E.P.). The specification is somewhat cryptic and [*3] provides little more detail than would be provided in a specification submitted to the Department of Agriculture under the Plant Variety Protection Act. There is no section therein explaining "the nature and gist of the invention or the inventive concept." (See the suggestion set forth in M.P.E.P. § 608.01(a), Form Paragraph 6.02). Importantly, the specification has little specific language which distinguishes the claimed soybean variety from other soybean varieties and does not explain the significance of any differences in attributes between the novel variety and varieties that are old in the art. See 37 CFR § 1.71 (b). n2

n2 37 CFR 1.71(b) reads as follows:

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

A problem has arisen during prosecution because, [*4] not knowing the nature and gist of the invention and what appellant regards as the inventive concept, the examiner has had considerable difficulty examining the application, especially with regard to formulating a conclusion of obviousness. On this point, the examiner notes that while appellant's soybean variety is a cross between two different varieties, appellant's specification does not advise the reader as to (1) the characteristics possessed by each parent variety, (2) which of these characteristics were expected to be passed on to progeny plants, and (3) what inheritable characteristics (goals) were sought in the progeny. The examiner also complains that the specification does not reveal what important characteristics were needed, but lacking, in prior varieties of soybeans and whether the claimed crossbreed (hybrid) fulfilled the need. In other words, the examiner is of the opinion that the instant specification lacks the specific technological "background" information necessary for the examiner to assess whether or not the claimed invention meets the statutory prerequisites for the grant of a patent.

Appellant's specification has been "objected to" by the examiner [*5] because, in her words, the specification fails "to provide (a) full written description, and (b) enablement and best mode of practicing the claimed invention." The claims are also "rejected" under 35 U.S.C. § 112, first paragraph, for the same reasons.

There are significant legal and procedural distinctions between an "objection" and a "rejection." An "objection" to the specification indicates that the specification is not satisfactory to the examiner because it does not conform to certain criteria established by (a) the patent statute, (b) the Patent and Trademark Office rules of practice, or (c) conventions and customary practices which have evolved over the years. A "rejection" constitutes an adverse decision by the examiner denying the grant of a patent for the subject matter claimed on the ground that the invention as set forth in the claims does not meet the requirements imposed by Congress in the patent statute.

In this case, that part of the examiner's "objection" which centers on description, enablement and best mode concerns the correspondence of the specification to the statutory requirements set forth in 35 U.S.C. § 112 and is within the jurisdiction of this Board. [*6] However, that part of the "objection" which relates to the examiner's desire for

information concerning (a) an explanation of the "gist" of the invention, (b) the phenotypic characteristics of the parent plants and the inheritability thereof, and (c) the goals sought to be achieved by the inventors, relates solely to the ease and accuracy of the examination process and the ability of the examiner to obtain sufficient information therefrom to effectively examine the application. It concerns either the rules of practice or established customs and practices. It is outside the jurisdiction of this Board. n3

n3 35 U.S.C. § 134, which provides the right of appeal, refers only to the appeal of rejections of claims and, accordingly, restricts the jurisdiction of the Board of Patent Appeals and Interferences to considering the propriety of "rejections." The propriety of "objections" and other procedural requirements is solely within the jurisdiction of the Commissioner of Patents. In re Hengehold, 440 F.2d 1395, 169 USPQ 473 (CCPA 1971). See also In re Haas, 486 F.2d 1053, 179 USPQ 623 (CCPA 1973) regarding "objections" which are de facto rejections.

When the specification [*7] is "objected to" and the claims are "rejected" for the same reasons, consideration of the propriety of the objection is usually held in abeyance because the Board's decision may well be dispositive of both the "objection" and the "rejection." "New Matter" questions often fall into this category. In this instance, however, the examiner's "objection" and "rejection" cover somewhat different territory and our decision with regard to the examiner's "rejections" may not be dispositive of all "objections."

ENABLEMENT

We consider first the examiner's rejection under 35 U.S.C. § 112, first paragraph. It is the examiner's position that the claims are based on a disclosure which does not enable one skilled in the art to make the claimed * * * variety of soybean plant and seeds and does not set forth the best mode of carrying out the invention. More specifically, it is the examiner's position that the description of "how to make" the invention by crossing two varieties omits significant information concerning the breeding process, the selection pressures for disease resistance, the methods of measuring and testing resistance, etc. In the examiner's opinion, one of ordinary [*8] skill in the art could not independently develop the * * * plant and seed claimed herein following the general procedures set forth in the specification.

Appellant urges that even if exacting directions for crossbreeding and selection were detailed, one could not follow the directions to obtain the same * * * variety but, rather, would arrive at a substantially similar but yet different variety of plant. Appellant has offered to deposit seeds of the * * * soybean variety in the American Type Culture Collection (ATCC), a public depository recognized by the United States Patent and Trademark Office. Appellant urges that planting the deposited seed is the best mode of making new plants and seed.

There is no question that one having * * * seeds available through the ATCC depository would be enabled to grow a * * * plant and produce additional seeds therefrom. The procedure to be used by appellant to deposit seeds of the plant does not differ from that used to deposit a culture of microorganism as sanctioned by the Court of Customs and Patent Appeals in In re Argoudelis, 434 F.2d 1390, 168 USPQ 99 (CCPA 1970) and accepted by the Patent and Trademark Office in Section 608.01(p) [*9] of the M.P.E.P. as an alternative procedure for meeting the requirements of 35 U.S.C. § 112 for "biological material". We see little difference between the concept of screening a microorganism to develop a desired strain, which was before the court in Argoudelis, and the concept of screening plants to develop a desired variety which is before us now. Appellant has disclosed the parent varieties crossed and provided a general description of the selection process. An exacting description relating to how to select for the desired plant could only detail an experimental screening program which would not necessarily result in the exact same plant being obtained but, rather, would result in one which, though different, would have virtually the same characteristics. We are in agreement with appellant that upon deposit of the seeds in the ATCC the specification satisfies the enablement and best mode requirements of 35 U.S.C. § 112.

DESCRIPTION

We consider next the examiner's rejection under 35 U.S.C. § 112 for lack of description. This rejection has two aspects. In its first aspect, the examiner notes that certain language used by appellant to describe the plant variety is [*10] considered as inherently so indefinite that one skilled in the art is unable to identify the plant variety and distinguish it from other species. The particular language of concern relates to (a) the plant variety's susceptibility to disease, (b) its peroxidase content, and (c) its allegedly "superior yield."

The examiner's concern with the language of the specification cannot serve to substantiate the rejection of the claims under the first paragraph of 35 U.S.C. § 112. Appellant's specification sets forth a reasonable description of the characteristics of the seed and plant including, flower color, plant type, maturity group, bacterial resistance, nematode resistance, etc. The specification also names the parent plants used to obtain the claimed cross. As noted by appellant on pages 3 and 4 of the Reply Brief, there is sufficient information of record to establish that the language objected to is accepted by the art as descriptive of the characteristics of a soybean variety. We reverse with regard to this first aspect of the rejection under 35 U.S.C. § 112.

In its second aspect, the examiner asserts that the written description set forth in the specification fails to adequately [*11] describe the invention or breeding goals in terms that make the invention searchable as a whole. The examiner states unequivocally that she would want to know additional information concerning each of the parent varieties which were crossed to obtain the claimed plant. She indicates that traits which were known features of the parent lines directly relate to the obviousness issue because many of these traits may well be expected to occur in the progeny. The examiner wishes to be apprised of the selection procedure used by appellant because she wants to know whether the particular traits or characteristics of the claimed variety were expectations based on known characteristics of the parents or fortuitous variations observed in a selection procedure designed to select for something other than what was achieved. The examiner also wants to know why the varieties 'Pella' or 'Pella 86' are considered by appellant to be closest to that claimed. In other words, the examiner's concern is that appellant's specification does not serve to distinguish the invention from other things before known and used such that a proper examination and consideration of the obviousness issue may be [*12] made.

Appellant urges, on the other hand, that a disclosure must be considered adequate if it meets the requirements of 35 U.S.C. § 112. Appellant urges, "[T]here is no requirement that an application must be drafted in order that an Examiner can formulate a search" (Reply Brief, page 2).

We are in agreement with appellant that there is nothing in 35 U.S.C. § 112 which supports a rejection on the ground that the specification does not provide enough information for the examiner to formulate a search and examine the application.

The examiner has pointed to no case law which indicates that a disclosure which describes an invention and enables the practice of that invention in accord with 35 U.S.C. § 112, in this case by depositing in a public depository the seed necessary for the practice of the invention, must also include additional information to assist in the examination process and make easier the examiner's search and patentability determination. The claimed soybean is described in the specification to the extent that there is no question that appellant was in possession of the invention as of the time the instant application was filed. Because seed is to be deposited [*13] in a public depository, the specification is enabling and sets forth the best mode of carrying out the invention. While the examiner may want to possess additional information regarding the inventive process, in this case the inheritable characteristics of parent species of plants and the particular procedure used to select for the claimed plant, in order to carry out a thorough examination, there is nothing in the statute which commands its inclusion in the specification.

There is no question, however, that the description, enablement, and best mode requirements of 35 U.S.C. § 112 are but the bare minimum mandated by the statute and "are not the maximum that can be demanded in an application." In re Davies, 475 F.2d 667, 177 USPQ 381, 385 (CCPA 1973). As stated by the court of Customs and Patent Appeals in In re Argoudelis, supra, 434 F.2d 1393, 168 USPQ at 102, the disclosure of a patent application must not only be sufficient "to preclude the possibility that a patent could issue without any person skilled in the art being thenceforth enabled to make and use the invention," but also must be sufficient "to permit a thorough examination by the Patent [and Trademark] Office." [*14] n4 (We note, for example, that the Patent and Trademark Office rule which relates to the deposit of biological materials specifically requires the specification to include sufficient description of the deposited material not only to specifically identify it but also "to permit examination.") n5

n4 See also Judge Baldwin's concurring opinion in Argoudelis, supra, 434 F.2d at 1395, 168 USPQ at 104, wherein it is stated:

Practical necessity, of course, requires that an application disclosure be intelligible and capable of evaluation *before* the issue date. The examining bodies of the Patent Office must be able to understand what a claimed invention is, how it works, what utility it might possess, before they can adequately determine whether such invention merits the grant of a patent.

n5 37 CFR § 1.809(d) (3) reads as follows:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
- (1)...;
- (2)...;
- (3) a description of the deposited biological material sufficient to specifically identify it and to permit examination.
 - $(4) \dots;$

Though there is nothing in the patent statutes which mandates inclusion in the specification of information [*15] which the examiner considers important (a) with regard to distinguishing the claimed invention from other inventions and from what is old, and (b) with regard to whether to allow the application to issue as a patent, there is nothing in the patent statutes which precludes the examiner's requiring such information be included. Such a requirement, however, must be made by way of "objection" and is not within the jurisdiction of this Board. Because it is outside our jurisdiction, we reverse pro forma that aspect of the rejection under 35 U.S.C. § 112 (first paragraph) which pertains to the searchability of the invention described in the specification.

OBVIOUSNESS

Claims 5 through 8 stand rejected under 35 U.S.C. § 103 as obvious over the soybean varieties described in the documents identified as GRIN accession numbers SNB112 ('Pella') or P188447 (Chinese soybean), each in view of the combined teachings of Athow, Russell and Keeling. It is the examiner's position that although the prior art 'Pella' and Chinese soybean plants differ from the claimed plant in pod color, pubescence color and *Phythophthora* root rot resistance, the claimed invention would has been obvious, [*16] nevertheless, because (a) the color differences fall within the known range of variation for the soybean species, and (b) the secondary references make obvious the breeding of *Phythophthora* rot resistance into the plants.

We have carefully considered all of appellant's arguments but, nevertheless, are unpersuaded of error in the examiner's basic position and, accordingly, we affirm the rejection.

The claimed plant does not appear to differ significantly from the prior art plants as measured by numerous characteristics. Both the claimed plant and the prior art plant, SNB112 ('Pella'), are similar in color. Each has purple flowers and yellow seeds. 'Pella' has tan pod color versus brown pod color for the claimed plant. Both plants differ slightly in pubescence color and hila color, but both belong to maturity group III and has approximately the same oil yield. The Chinese soybean plant is even more similar in color and has similar oil yield and protein content.

As noted by the examiner, the secondary references teach that it is well known to breed root rot resistance into a plant by crossing the plant with other varieties having resistance to root rot. Accordingly, we are [*17] in complete agreement with the examiner that it would have been obvious to modify the soybean varieties of the primary references in order to impart root rot resistance to the plants. That this is so is evidenced by an admission made by appellant in the Petition to the Commissioner dated January 22, 1991, wherein appellant advises that the soybean variety 'Pella 86' is a version of 'Pella' having rot resistance conferred thereto using back crossing techniques in association with non-resistant 'Pella' and, necessarily, a variety having root rot resistance.

Appellant urges that the declaration of * * * reveals that the claimed variety is unobvious because it outyields 'Pella 86' and is "shorter than 'Pella 86" and more resistant to brown stem rot and to charcoal rot.

We have reviewed the data and the declaration but are unpersuaded of patentability because there is nothing of record which explains why the differences between the claimed variety and a rot resistant variety such as 'Pella 86' are so significant and unexpected that they should weigh more heavily than the numerous similarities between the claimed variety and the varieties of the cited prior art.

We remind appellant [*18] that in submitting evidence asserted to establish differences and/or unobvious results sufficient to dissipate a prima facie case of obviousness, there is a burden on the patent applicant to establish not only that the differences in results achieved are in fact "unexpected and unobvious" but also to establish that the differences are of practical significance. See In re Merck, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Klosak, 455 F.2d 1077, 173 USPQ 14 (CCPA 1972); In re D'Ancicco, 439

F.2d 1244, 169 USPQ 303 (CCPA 1971) and In re Freeman, 573 F.2d 1237, 197 USPQ 464 (CCPA 1978). See also the recent decision of this Board in Ex parte Gelles, 22 USPQ2d 1318 (BPAI 1992).

We note, for instance, that it may not be unexpected that the claimed cross is shorter than 'Pella 86.' It must be borne in mind that root rot resistance was introduced into the claimed variety by breeding 'Pella' with * * * The materials submitted by appellant on March 26, 1990 include a plant variety protection application for * * * describing it as a variety specifically bred for its rot resistance. The data therein [*19] indicates that the plant height of * * * is only 71 cm. It is not necessarily unexpected that the breeding of 'Pella' with the shorter variety * * * would not only impart rot resistance but also result in shorter progeny.

With regard to the rejection over Chinese soybean, appellant urges that there is a difference in the flowering and maturity dates but presents no evidence on this point. It is well settled that in order to overcome a prima facie case of obviousness, there is a necessity for "clear and convincing evidence" of unobvious results. In re Lohr, 458 F.2d 1013, 137 USPQ 548 (CCPA 1963). Counsel's unsupported arguments and allegations cannot take the place of that evidence. In re Greenfield, 571 F.2d 1185, 197 USPQ 227 (CCPA 1978).

We has carefully reviewed appellant's specification and find nothing therein which establishes a base for judging whether the differences asserted by appellant are, in fact, significant and unexpected. The specification says nothing regarding the significance and relative importance of such criteria as maturity date, shortness of plant, flower color and flowering date. The specification offers nothing regarding whether or not [*20] each parent variety crossed to develop the claimed variety was possessed of desirable characteristics or, alternatively, known to have recessive genes for the desirable characteristics, which genes would be expressed in the progeny upon crossing. Accordingly, we are unable to ascertain whether or not the particular features attributed to the claimed * * * variety and relied on by appellant for patentability are sufficiently significant and unexpected to dissipate the examiner's *prima facie* case.

In a somewhat analogous situation, the Court of Customs and Patent Appeals in *In re Davies*, 475 F.2d 667, 177 USPQ 381 (CCPA 1973) noted that "the public will derive the most benefit from a patent when it discloses on its face those properties or utilitarian advantages which were ultimately persuasive on the question of nonobviousness" (emphasis added). In the case before us, appellant's specification places no more emphasis on shortness of plant and bacterial resistance than on flowering date, flower color or hila color. Absent an explanation of relative significance in either the specification or the submitted declaration, it is virtually impossible for the decision maker [*21] to conclude that the dissimilarities argued by appellant outweigh the similarities proffered by the references.

Claim 5, which is directed to the specific process of producing * * * seed by "self-pollinating" * * * soybean plant, has been separately rejected as directed to a pollination process which, albeit performed by novel soybeans, was well-known in the art and in use long before the instant invention was made. The examiner relies on *In re Durden*, 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985) and has taken the position that despite the novelty of the plant and the seed, the claimed process is an old one and, accordingly, is unpatentable.

Appellant urges that the claimed process is "a process of using" a new variety of soybean plant and is patentable as a "process of using" under the rule espoused in *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990) and *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974). This argument has been countered by the examiner who notes that the preamble of claim 5 designates the process as a "method of producing," i.e., "making" seeds.

We affirm the examiner's rejection. For reasons set forth above, we are in [*22] agreement with the examiner that the claimed * * * variety of plant and, accordingly, the claimed process inherent in the ordinary use of that plant, would have been obvious to one of ordinary skill in the art at the time the invention was made.

PUBLIC USE OR ON SALE

Claims 5 through 8 stand rejected under 35 U.S.C. § 102(b) on the grounds that the invention was "in public use," or "on sale," more than one year prior to the filing of the instant application.

The "public use or on sale" rejection was engendered by an Information Disclosure letter submitted by appellant on June 25, 1990 (Paper No. 7). This letter advised the examiner that it is standard practice in the soybean art to transfer seedstock of a new plant variety to "growers" who are paid a fee to plant the seedstock and increase the inventory of seed available for sale when the new variety of seed is announced via publication in a seed catalog. The letter also advises that the growers pay applicants' assignee a fee for use of the seed and the grower returns all the harvested seed for subsequent sale to farmers. The Information Disclosure letter indicates that applicants' assignee retains title to all seed produced [*23] by the grower, the grower returns all the harvested seed to the assignee and the grower, by

contract, does not have the right to sell, dispose of, use or otherwise encumber the seed or permit another to sell, dispose of, use or otherwise encumber the seed. A copy of a blank contract was attached to the Information Disclosure letter.

The examiner's rejection has two aspects, "public use" and "on sale." We consider first the "on sale" aspect of the rejection. We affirm the examiner's rejection noting that there are clauses in the contract which trigger the "on sale" bar.

Clause 1, on the back of the blank contract, indicates that title to the seed does not normally vest in the grower and that applicants' assignee remains the owner of the seed and the crop produced therefrom. Because title does not leave the assignee and does not vest in the grower, it would appear that Clause 1 negates interpretation of the contract as one of "sale." As noted by the examiner, however, there are certain unnumbered paragraphs of the contract relating to "quality" and "acceptance and payment" which contain special provisions (conditions) therein which, if activated, cause title to vest immediately [*24] in the grower. Accordingly, because the grower has paid for the seed, a sale may be accomplished under the contract when and if the special contract provisions are activated. The contract may properly be viewed as one of "conditional sale."

More specifically, the contract has an "acceptance and payment" clause which has a blank space therein which sets the percentage of the "growers contracted production" of soybeans which will be accepted by the company. Any amount of total production not accepted by the company is deemed "rejected for seed use" such that the terms of paragraph 8 apply to that seed. Paragraph 8 specifically states that title to "rejected seed" immediately vests in the grower and the rejected seed constitutes the growers entire compensation thereunder. Should the blank of the acceptance and payment clause be filled in with any number less than 100%, an actual sale would occur as of the date the contract is entered into because a predetermined quantity of "rejected seed" may be considered as constituting payment for the growers' services. The grower has the right to use rejected seed for purposes other than planting.

The soybean contract also includes a "quality" [*25] clause which indicates that the company is not obligated to accept any portion of the contracted production which does not comply with the quality standards established regarding moisture content, "clean out" and germination, or is denied "certification" for any reason. The "quality" clause establishes conditions which relieve the company of obligation to accept any portion of the contracted production as seed. Necessarily, that portion not accepted will be considered "rejected" seed covered by clause 8 of the contract. Title to said rejected seed vests immediately in the grower. We are in agreement with the examiner that should the "quality" clause be activated, the contract would clearly evidence a sale. More importantly, during the life of the contract the assignee was never obligated to accept rejected seed, and at all times during performance of the contract there was a distinct possibility that title could change hands. This is sufficient to trigger the "on sale" bar. no 35 U.S.C. § 102(b) does not require an actual sale but only that the material be "on sale." We affirm the examiner's rejection.

n6 Appellant argues that the "quality" clause was never activated and that all seed was accepted by the assignee. Arguments by counsel cannot take the place of factual evidence. *In re Greenfield, 571 F.2d 1185, 197 USPQ 227 (CCPA 1978)*. Moreover, the assignee was never under an obligation to accept seed which was of poor quality. This lack of obligation to accept poor quality seed converted the contract into a "conditional sales" contract. [*26]

We consider next the public use aspect of the invention. As best we understand this rejection, it is the examiner's position that the use of seed by the grower, a third party, to produce and accumulate assignee's inventory of seeds, for eventual sale in the ordinary course of business, constitutes sufficient commercial activity to establish a "public use" of the claimed seed.

Appellant urges that there was no "public use" because the seed, although being produced and inventoried for sale, was not "on sale" at the time the seed was being produced. Appellant also argues that title to the seed did not pass to the grower and that the grower was heavily restricted regarding what could be done with the seed. We are unpersuaded by these arguments.

The fact situation before us is somewhat unique. The invention claimed herein was completed long prior to the filing date of the instant application (about 3 years prior). In this regard, the PVP certificate application indicates that the claimed soybean variety was developed by 1986 and that breeder seed was grown in 1987. Appellant has admitted that the use of the seed by growers was to produce and acquire seed for sale. Appellant has [*27] also admitted that the * * variety was eventually advertised, the seed was sold in the due course of business and that the amount of seed

required to supply the market is "literally millions of pounds" (Brief, pages 12, 13). The growers contract does not contain a secrecy clause.

"Public use" of a claimed invention under section 102(b) has been defined as any use of that invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor. Egbert v. Lippmann, 104 U.S. 333, 336 (1881); In re Smith, 714 F.2d 1127, 218 USPQ 976 (Fed. Cir. 1983). In the case before us the claimed seeds and plants were used by the growers to produce new plants and seeds. There is no evidence of record of a secrecy agreement between the grower and appellant. A prima facie case of public use has been made out.

The Federal Circuit recognizes four underlying policies behind the section 102(b) bar. These policies are set forth in King Instrument Corporation v. Otari Corporation, 767 F.2d 853, 226 USPQ 402 (Fed. Cir. 1985) as follows:

- (1) discouraging removal of inventions from the public domain which the public justifiably [*28] comes to believe are freely available.
 - (2) favoring prompt and widespread disclosure of inventions;
- (3) giving the inventor a reasonable amount of time following the sales activity to determine the value of a patent; and,
 - (4) prohibiting an extension of the period for exploiting the invention.

Policies (2) and (4) are applicable herein.

Even if there was an obligation of secrecy and confidentiality this does not necessarily avoid the public use bar. See T. P. Laboratories, Inc. v. Professional Positioners, Inc., 724 F.2d 965, 220 USPQ 577 (Fed. Cir. 1984). Indeed, in D. L. Auld Co. v. Chroma Graphics Corp., 714 F.2d 1144, 219 USPQ 13 (Fed. Cir. 1983), the court indicated that the statutory scheme of 35 U.S.C. § 102(b) was to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed. The public use proscription in 35 U.S.C. § 102(b) prohibits "commercial activity," i.e., the competitive exploitation of the invention by the inventor or his assigns after it is ready for patenting; the reason being that "it is part of the consideration for a patent that the public shall [*29] as soon as possible begin to enjoy the disclosure." See Metallizing Engineering Co. Inc. v. Kenyon Bearing & Auto Parts, Inc., 153 F.2d 516, 68 USPQ 54, 58 (2nd Cir. 1946).

As noted by the examiner, the grower was an independent contractor under no obligation of secrecy. The grower paid for the seed and suffered all risk of damage to a loss of the crop. Title to poor quality seed or unpurchased seed was to vest in the grower. We are of the opinion that on the facts of this case, use of the seed, by growers, with no special requirements for secrecy and confidentiality constituted commercial activity towards a competitive advantage. In this regard see *Bourne v. Jones, 114 F.Supp. 413, 98 USPQ 206 (S.D.Fla. 1951)*, wherein similar activity involving the growing of seed cane by growers was considered to be a "definite commercial use in that the growers were expanding available seed to full scale production." We recognize that the growers of *Bourne* were (a) independent of the inventor, (b) not subject to the inventor's control, (c) unaware of any restrictions at the time of their use, and (d) made use of the canes for their own purposes. Nevertheless, in this case it is [*30] "commercial activity", i.e., use of the seed by third party growers to produce large quantities of seed for eventual sale, coupled with the "on sale" aspects of the grower's contract and the apparent lack of secrecy and confidentiality requirements which constitutes the proscribed public use. We affirm the examiner's rejection.

The examiner's rejections of claims 5 through 8 under 35 U.S.C. § 112 (first paragraph) are reversed.

The examiner's rejections of claims 5 through 8 under 35 U.S.C. § 103 are affirmed.

The examiner's rejections of claims 5 through 8 under 35 U.S.C. § 102(b) (public use and on sale) are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a). See the final rule notice, 54 F.R. 29548 (July 13, 1989), 1105 O.G. 5 (August 1, 1989).

AFFIRMED

CONCURBY: GOLDSTEIN; SMITH

CONCUR:

Goldstein, Examiner-in-Chief, specially concurring:

I agree with the majority with respect to its decision of the appeal of every appealable rejection. I disagree, however, with the majority's apparent acceptance of appellant's assertion that "[t]here is no requirement that an application must be drafted in order that an examiner [*31] can formulate a search." In my opinion, there is such a requirement. It is found in the second paragraph of 35 U.S.C. 112, and a rejection under that paragraph of Section 112 would have been appropriate.

With regard to the second paragraph requirement for "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," it has been stated that the "essence of that requirement is that the language of the claims must make it clear what subject matter they encompass." In re Hammack, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970). This has been frequently stated in a shortened form as a requirement that the claims set forth the "metes and bounds" of their coverage. See, merely for example, In re Venezia, 530 F.2d 956, 958, 189 USPQ 149, 151 (CCPA 1976); In re Goffe, 526 F.2d 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); In re Watson, 517 F.2d 465, 477, 186 USPQ 11, 20 (CCPA 1975); In re Knowlton, 481 F.2d 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). This requirement has usually been viewed from the perspective of a potential infringer, "so that they may more readily and accurately determine the boundaries of [*32] protection involved and evaluate the possibility of infringement and dominance." 427 F.2d at 1382, 166 USPQ at 208. However, there is authority to support the proposition that the second paragraph requirement is also for the purpose of enabling comparison of the claimed subject matter with the prior state of the art, i.e., enabling examination.

In In re Steele, 305 F.2d 859, 134 USPQ 292 (CCPA 1962), a rejection under 35 U.S.C. 103 was formally reversed. In suggesting that the claims should "be reviewed to insure compliance with 35 U.S.C. 112," the court pointed out that, before claimed subject matter can properly be compared to the prior art, it "is essential to know what the claims do in fact cover" (emphasis supplied). The same proposition can be found to be at least strongly implicit in the decisions in In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971), and In re Merat, 519 F.2d 1390, 186 USPQ 471 (CCPA 1975). The decision in the former case stated that, if upon analysis the claims were found to be indefinite under the second paragraph of 35 U.S.C. 112, they could not even be analyzed under the first paragraph of 35 U.S.C. 112, because that analysis of [*33] the claims could not be carried out unless one was able "to determine exactly what subject matter they encompass[ed]." This reasoning would clearly apply equally well to an analysis of the claims with regard to the prior state of the art. In the latter case, the court stated that its affirmance of the 35 U.S.C. 112, second paragraph, rejection rendered it "unnecessary to discuss the other grounds of rejection," which included a rejection under 35 U.S.C. 103 based on the prior state of the art. Of course, the portion of the concurring opinion in Argoudelis quoted in footnote 3 of the majority opinion here, albeit it is from a concurring opinion, is at least further evidence that the proposition set forth here is correct.

In the event of further prosecution of this subject matter before the examiner, I firmly recommend that a rejection be made under the second paragraph of 35 U.S.C. 112 on the basis of the issue raised by the examiner in objecting to the specification, i.e., that the claims read in light of the specification could not be examined with regard to the prior state of the art. When the issue has been raised under the proper paragraph of Section 112, it may be more [*34] readily developed and, in the event of a subsequent appeal, more appropriately briefed.

John D. Smith, Examiner-in-Chief, concurring:

The majority affirms the examiner's "on sale" rejection of the appealed claims under 35 U.S.C. § 102(b) in part on the grounds that at all times during performance of the contract there was a distinct possibility that title could change hands. Although I concur with the result reached by the majority with respect to this rejection, I am aware of no legal precedent, nor have appellants or the majority cited any, which holds that a patent defeating "sale" under 35 U.S.C. § 102(b) requires a transfer of title of the property.

A "sale" has been broadly defined as a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay to the seller for the thing bought or sold, 77 C.J.S. Sales § 1 (1952), and this broad definition has been applied to a "sale" as defined by 35 U.S.C. § 102(b). In re Caveney, 761 F.2d 671, 226 USPQ 1 (Fed. Cir. 1985). Here, the contract requires the grower to purchase seed from applicant's assignee in exchange for a valuable property right, the right to use [*35] the seed by planting it for the purpose of producing a new plant which produces more seed. Although the grower cannot use any rejected seed for planting purposes, the implied right to plow under the new plant produced to fertilize the grower's acreage is itself a valuable "right of property." Moreover, as noted by the majority, the grower has the right to use rejected seed for purposes other

than planting. Thus, in my view, any purchasing of seed by a grower constitutes an actual "sale" under 35 U.S.C. § 102(b).

With the exception noted above, I agree with the majority with respect to its decision of the appeal and its reasoning regarding all other rejections.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit 1638

In re

Patent Application of

Paul Sun, et. al.

Application No. 09/773,976

Confirmation No. 6280

Filed: January 31, 2001

Examiner: Fox, David T.

"ALFALFA HYBRIDS HAVING AT LEAST 75%

HYBRIDITY"

I, Mary A. Hietpas, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on the date of my signature.

Signature

ale of Signature

APPEAL BRIEF UNDER 37 CFR 1.192

Mail Stop APPEAL BRIEF-PATENTS Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Concerning the above-referenced patent application, the Appellants have appealed from the final rejection of claims 1-9, dated June 2, 2003. Appellants are submitting this Appeal Brief in triplicate in support of their appeal. A check in the amount of \$165 is submitted in payment of the official filing fee. A request for a two-month extension of time and a check in the amount of \$210 is also being submitted herewith, extending the deadline for filing the Appeal Brief to January 2, 2004.

REAL PARTY IN INTEREST

The real party-in-interest is Dairyland Seed Co., Inc., to which the inventors have assigned their entire right, title and interest in and to the invention in assignment recorded May 14, 2001.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 1-9 are pending. Claim 10 is cancelled. Claims 1-9 stand rejected and appealed.

STATUS OF AMENDMENTS

In response to the first Office Action on the merits, an Amendment was filed on September 10, 2002, amending the specification, canceling claim 10 and amending claims 1, 2, 5, 7, 8 and 9. In an Office Communication mailed January 28, 2003, Appellants were informed that this Amendment was not entered because a marked-up version of the amendments to the specification was not submitted. Appellants resubmitted the Amendment on February 27, 2003, again amending the specification, canceling claim 10 and amending claims 1, 2, 5, 7, 8 and 9 and including marked up versions of the specification and claims. This Amendment was entered.

In response to the final Office Action, Appellants submitted an Amendment on September 2, 2003, in which claims 2 and 9 were amended. In an Advisory Action mailed October 30, 2003, Appellants were advised that the Amendment was entered.

¹ Claim 10 and an accompanying description of the claim as "cancelled" was inadvertently omitted from the previous Listing of Claims submitted with Applicant's Response of September 2, 2003.

SUMMARY OF THE INVENTION

The presently claimed invention is directed to a novel *Medicago sativa* hybrid cultivar designated DS9705Hyb. The novel culitvar exhibits agronomically desirable traits, including high forage yields, high seed yields, winter hardiness and improved disease resistance, among other beneficial characteristics. Additionally, DS9705Hyb hybrid plants exhibit improved uniformity in characteristics than is typically observed in hybrid breeding programs. In one aspect, the invention provides seeds of the DS9705Hyb hybrid, which are deposited under the Budapest Treaty with the American Type Culture Collection (Accession Number PTA-2759). The invention also provides alfalfa plants grown directly from the seeds deposited under ATCC Accession Number PTA-2759. Plants grown from a vegetative cutting, callus or tissue culture taken from a plant grown directly from the deposited seeds are also encompassed by the invention, as well as pollen and ovules from the plants.

The presently claimed invention is also directed to a novel method of producing alfalfa seeds having at least 75% hybridity, i.e., 75% of plants contain genetic traits of both parental lines. The claimed method includes steps of: crossing cytoplasmic male sterile alfalfa plants with maintainer alfalfa plants to produce cytoplasmic male sterile hybrid plants; selectively harvesting seed from the cytoplasmic male sterile plants; crossing male sterile hybrid plants by male fertile alfalfa plants by open pollination by growing the seed from male sterile hybrid plants with seed from at least one line of male fertile alfalfa plants, the male sterile and male fertile seed planted at a ratio of about four male sterile seeds to one male fertile seed; and non-selectively recovering seeds from the pollinated alfalfa plants. The method of the invention differs from traditional hybrid breeding methods in that about a 4:1 planting ratio of male sterile and male fertile seed is used to yield optimum results. A further optional step in the method

includes determining the hybridity of the progeny of the crossing. Optionally, hybridity is determined using morphological or genetic markers. If genetic markers are used to determine hybridity, the analysis may be done using amplified fragment length polymorphism ("AFLP") techniques. In a preferred embodiment, the method of the invention yields at least 80% of the average seed yield of the male fertile parental line.

STATEMENT OF THE ISSUES

The issues presented in this appeal are as follows:

- (1) Whether claims 1-9 are unpatentable under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention.
- (2) Whether claims 1-4 are unpatentable under 35 USC §102(b) as anticipated by Northrup et al. (Seed Scoop Vol. 19, No. 4. p. 6 (1972)).
- (3) Whether claims 2-4 are unpatentable under 35 USC §102(b) as anticipated by or, in the alternative, under 35 USC §103(a) as obvious over each of Northrup et al. and Thompson et al. (Crop Science Vol. 14, p. 609 (1974)).
- (4) Whether claims 5, 6 and 9 are unpatentable under 35 USC §103(a) as obvious over Sun et al. (U.S. Patent No. 4,045,912).
- (5) Whether claims 5-7 are unpatentable under 35 USC §103(a) as obvious over Sun et al. in view of Viands et al. (Ch. 30: Alfalfa and Alfalfa Improvement, Agronomy Monograph No. 29, Crop Sci. Soc. of America, pp. 931-960 (1988)).

(6) Whether claims 5 and 8 are unpatentable under 35 USC §103(a) as obvious over Sun et al. in view of Rotili et al. (Plant Science Vol. 32, No. 6, pp. 15-17 (1995) and further in view of Vos et al. (Nucleic Acid Research Vol. 23, No. 21, pp. 4407-4414 (1995).

GROUPING OF CLAIMS

For purposes of the substantive rejections under 35 USC §§ 112, 102 and 103, the rejected claims do not stand or fall together, and the following groups of claims are separately patentable:

Group I: Claim 1

Group II: Claims 2-4

Group III: Claims 5 and 9

Group IV: Claims 6-8

ARGUMENT

Introduction

It is respectfully asserted that the Examiner's misunderstanding of the invention, and the Examiner's repeated mischaracterization of the invention as a "synthetic variety" (when the evidence presented in the specification and prosecution history clearly and convincingly demonstrates that the invention is a hybrid variety) has led the Examiner to maintain the claim rejections in the present application. Appellants respectfully assert that consideration of the evidence of record and the arguments presented herein will lead the Board to reverse each of the rejections in the present case.

5

Rejection of Claims 1-9 Under 35 U.S.C. § 112, First Paragraph

The Examiner has maintained the rejection of the claims of Groups I-IV, asserting that claims 1-9 are unpatentable under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining what constitutes "undue experimentation" are set forth in *In re Wands*, 858 F.2d 731, 737; 8 USPQ 2d 1400 at 1404 (Fed. Cir. 1988): (1) the breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) level of one of ordinary skill; (5) level of predictability; (6) amount of direction or guidance provided; (6) existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure. For the reasons that follow, Appellants respectfully assert that the claimed invention may be practiced by the skilled artisan without undue experimentation.

Group I

With respect to Group I (claim 1), directed to a seed deposited as ATCC Accession

Number PTA-2759, the gravamen of the Examiner's position appears to be that the claim should
be broadly interpreted to cover any alfalfa seed "derived with the synthetic variety Thor." The

Examiner then asserts, in light of this broad interpretation, that Appellants have not provided
enabling disclosure sufficient to represent a synthetic variety.

Appellants respectfully assert that the Examiner's overbroad claim interpretation is not warranted in light of the specification and evidence of record. Appellants further assert that the claimed invention, when properly interpreted, is fully supported by an enabling disclosure.

The Examiner asserts that the claimed invention is indistinguishable from synthetic variety Thor because the specification includes a description of Thor in the parental lineage.

The Examiner is not correct. As taught by Fehr et al., cited by the Examiner, a hybrid is defined as "the first generation progeny from a cross involving inbred lines." Fehr et al., Principals of Cultivar Development, Ch. 33, p. 244 (1987). An inbred line is described as:

a pure line, or nearly homozygous line, usually developed by inbreeding. The source of inbreds may be an open-pollinated variety; a single-, three-way or double-cross hybrid; a synthetic variety; or a population improved through recurrent selection.

Id. (emphasis added). Thus, as is known in the art, the use of a synthetic variety for further hybrid development is <u>not</u> understood to render the derived hybrid variety a synthetic *per se* as the Examiner asserts.

In addition, the above definitions describing a hybrid closely track the present specification's description of the development of the claimed hybrid, further evidencing that one of skill in the art would understand the claimed invention to be a hybrid alfalfa, and not a synthetic. Compare Fehr et al., illustration at p. 244 with specification page 4, line 29-page 5, line 12. Based on the description in the specification, one skilled in the art would appreciate that the claimed invention was made using selected parental components, rather than a commercial variety. For example, the description of the method of the invention at page 4, line 29-page 5, line 12 (reproduced below with emphasis added), clearly indicates that the method employs selected lines or clones of alfalfa:

Briefly, the method of the invention is performed as follows:

1. Alfalfa plants with desirable agronomic traits are selected. Male sterile A line plants are selected from male sterile ("female") populations, maintainer B line plants are selected from maintainer populations, and pollenizer C line plants are selected from restorer populations, or from clonal or synthetic populations.

- 2. The selected A and B lines are grown from cuttings or seed and cross pollinated using bees to produce hybrid male sterile breeder and foundation seeds. Seeds are harvested from cytoplasmic male sterile plants only.
- 3. Selected pollenizer plants are selfed or interpollinated by bees to produce breeder and foundation pollenizer seeds and the seed is harvested in bulk.
- 4. For large scale commercial production of hybrids, male sterile seeds and pollenizer seeds are planted at a ratio of male sterile seeds and male fertile (pollenizer) seeds of about 4:1, and the plants grown therefrom are pollinated.
- 5. Seeds are harvested in bulk from the plants grown from the seed of step 4, above.
- 6. Optionally, the percentage hybridity can be determined using either genetic or morphological markers.

The Examiner has also broadly interpreted the names DS9705Hyb, A833, B209, DS9761, and C580 as "synthetic varieties." Contrary to the Examiner's interpretation of parental components A833, B209, Thor, DS9671, and C580 as being synthetic <u>varieties</u>, Appellants have described the plants identified by these terms as being alfalfa plant <u>lines</u> at least at page 6, lines 1-4 (emphasis added):

In the examples below, male sterile line A833, maintainer line B209, and **pollenizer lines** Thor, DS9671, and C580 were used. One of ordinary skill in the art will appreciate that any suitable male sterile line, maintainer line, and pollenizer line could be successfully employed in the practice of the method of the invention.

Further, throughout the specification, the Appellants made clear that the terms Thor, DS9671, C580, and B209 were intended to refer to using selected clones, or the S1 progeny of selected clones, rather than commercial varieties (e.g., page 7, lines 10-12). As inventor Dr. Sun explained in his Declaration at page 2, paragraph 7, another copy of which is attached hereto as Exhibit A, a pollenizer <u>line</u> is understood by one of skill in the art to mean "a group of individuals from a common ancestry, which is narrower than a strain or variety." One of ordinary

skill in the art would understand that a plant clone is a plant or group of plants originated by vegetative propagation from a single plant.

The specification clearly distinguishes between synthetic varieties (Vernal and Saranac), hybrids (A833 xB209, A833 xB209 (S1) and DS9750Hyb) and selected clones (Thor, DS9761, and C580). For example, on pages 7-10 of the specification, the Examples detail studies in which characteristics of hybrids produced according to the invention were compared with synthetic varieties (Vernal and Saranac) and selected clones (Thor, DS9761, and C580). Characteristics of hybrids of crosses between a male sterile line (A833) and a maintainer line (B209), and hybrid DS9705Hyb, the components of which include a cytoplasmic male sterile hybrid plant (A833xB209), and selected pollenizer lines were also compared with synthetic varieties on pages 11-24 (Tables 1-23)².

Importantly, not only do the Examples and Tables distinguish between synthetics, hybrid components and hybrids, but they also provide detailed guidance to the skilled artisan with respect to the parental components of the claimed hybrid seed and plant, which the Examiner has maintained is lacking. Contrary to the Examiner's position, the Examples and Tables provide the skilled artisan with information regarding the parental lines' plant size (in relation to commercial varieties Vernal and Saranac), winter survival rates, spring vigor assessments, flowering dates, flower color, pollen production index, disease resistance, forage yield and seed yield.

Moreover, precedent of the Board has established that with respect to a hybrid plant, a deposit of seed enables claims to the seed. In Appeal No. 92-0393 from Art Unit 1804, 27

² In the Advisory Action, the Examiner asserts that the Tables on pp. 15-17 and 21-22 indicate that DS9705Hyb is a synthetic. This is inaccurate. The Tables inadvertently included "Syn Gen" as a column heading, but should instead read simply "Gen." For the reasons asserted herein, however, one of skill in the art would appreciate that the listed lines and hybrids are not synthetics, despite the typographic error in the column headings.

USPQ2d 1492 (BPAI 1992)³, a case with facts strikingly similar to this one, the claims were directed to a method of producing a hybrid soybean plant, the hybrid soybean plant, the seed which produced the hybrid soybean plant and seed produced by the hybrid soybean plant. The Examiner rejected the claims under 35 USC § 112, first paragraph. It was the Examiner's position that because the specification omitted information concerning the breeding process, the selection pressures for disease resistance, the methods of measuring and testing resistance, etc., one of ordinary skill in the art could not independently develop the claimed hybrid. The Appellant offered to deposit the seeds with the ATCC. The Board held that the availability of the seeds through the ATCC depository enabled one of skill in the art to grow a plant and produce additional seeds therefrom. The Board stated:

An exacting description relating to how to select for the desired plant could only detail an experimental screening program which would not necessarily result in the exact same plant being obtained, but, rather, would result in one which, though different, would have virtually the same characteristics. We are in agreement with the appellant that upon deposit of the seeds in the ATCC, the specification satisfies the enablement and best mode requirements of 35 USC § 112.

In light of the description of the characteristics of the parental lines in the present case and the ATCC deposit of the claimed hybrid seeds, Appellant respectfully request that the Board reverse the rejection of claim 1 under 35 USC § 112.

Group II

Claims 2-4 (Group II) are directed to plants grown directly from the seed deposited as ATCC Accession Number PTA-2759, or plants grown indirectly (i.e., clonally or from

³ For the convenience of the members of the Board, a copy of the published decision is attached as Exhibit B.

vegetative cuttings, etc.) from the seed deposited as ATCC Accession Number PTA-2759, and pollen and ovules produced from the plants grown directly from the deposited seed.

For the many of same reasons that the claim to the deposited seed is enabled by the specification in light of the ATCC deposit, *a fortiori*, claims to a plant grown therefrom, or grown indirectly from a plant grown therefrom, are enabled as well. It is elementary that a party in possession of the claimed deposited seeds would be able to make and use the claimed hybrid plants by simply planting and cultivating the seeds. Once in possession of the plants, that party would also be able to obtain pollen (claim 3) and ovules (claim 4), as well as produce additional plants via a vegetative cutting, callus or tissue culture. As stated by the Board, "there is no question that one having seeds available through the ATCC depository would be enabled to grow a plant and produce additional seeds therefrom." Appeal No. 92-0393 from Art Unit 1804, 27 USPQ2d 1492 (BPAI 1992).

In the Advisory Action, however, the Examiner states that claim 2 "reads on somaclonal variants, since it has been amended to encompass plants grown from tissue or callus, which are known to generate somaclonal variants which do not have the same genotype or phenotype as the plants from which they are obtained." The Examiner ignores the fact that at least some culture-derived plants are necessarily genetically the same or nearly the same as the plant from which the cultured cells were derived. Screening for the desired plants and eliminating somaclonal variants are tasks well within the skill in the art. Thus, despite the biological possibility of somaclonal variants, the skilled artisan is nevertheless enabled to make and use the claimed hybrid plant without undue experimentation.

Group III

Claims 5 and 9 (Group III) are directed to a method of producing alfalfa seeds having at least 75% hybridity, and in one claimed embodiment, a method wherein the average seed yield is at least 80% of the average seed yield obtainable by selfing the male fertile plants obtained in the second crossing step recited in the method. With respect to these claims, the Examiner asserted that methods of producing alfalfa seeds having 75% hybridity are subject to biological constraints such that the open pollination planting ratio claimed (i.e., 4:1) would not ensure a hybridity of at least 75% or a yield of 80% "in consideration of the totality of all alfalfa plants of differing pollen fertility as broadly claimed." Office Action dated 3-15-2002, pp. 8-9 (emphasis added). Even assuming arguendo that the Examiner's proposition (for which no authority whatsoever is cited) is correct, in light of the high level of skill in the art and the guidance provided in the specification, Appellants assert that performing the claimed method is nevertheless enabled.

The necessary corollary to the Examiner's assertion is that to be enabled, the claims to methods of producing alfalfa plants must "ensure" 75% hybridity and 80% yield. This is not the standard of 35 USC § 112, first paragraph. Some experimentation by the skilled artisan is permissible, as long as it is not "undue." Factors to be considered in determining what constitutes "undue experimentation" are: (1) the breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) level of one of ordinary skill; (5) level of predictability; (6) amount of direction or guidance provided; (6) existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In* re Wands, 858 F.2d 731, 737; 8 USPQ 2d 1400 at 1404 (Fed. Cir. 1988). Here, at least the state

of the art, the level of ordinary skill in the art, and the amount of guidance and working examples provided in the specification weigh in favor of enablement of the claims of Group III.

With respect to the state of the art, the Examiner has recognized⁴ that Sun et al., U.S. Patent No. 4,045,912, incorporated by reference in the present specification, teaches a process of producing hybrid alfalfa seeds which comprises crossing by controlled pollination cytoplasmic male sterile alfalfa plant with maintainer line alfalfa plants to provide hybrid male sterile alfalfa seeds, selectively recovering the hybrid seeds, crossing by random pollination, plants derived from the hybrid seeds randomly mixed with male fertile plants in ratio of 1:1 to 3:1 and non-selectively recovering the seeds from the crossing. Col. 11, lines 38-54. Thus, the state of the art at the time of filing the present invention, while failing to teach or suggest all required elements of the present claims, had nonetheless advanced regarding the production of hybrid alfalfa seed.

The level of skill in the art of plant breeding and development of plant varieties is high.

Finally, as noted above, the present specification provides detailed guidance regarding the method of the invention and the development of an example, DS9705Hyb, produced according the method of the invention, including measurements of its properties and comparisons to properties of parental components and synthetic varieties.

Therefore, Appellants respectfully assert that the invention claimed in Group III is wholly enabled in light of the guidance and examples provided in the specification, the high level of skill in the art, and the state of the prior art and therefore request that the Board reverse the rejection.

⁴ See rejection under 35 USC § 103/102(b) over Sun et al.

Group IV

Claims 6-8 (Group IV) are directed to methods of producing alfalfa seeds having at least 75% hybridity, further including a step of determining the hybridity of the progeny of the crossing.

With respect to Group IV, the Examiner asserts that Appellants have failed to provide sufficient guidance as to how one would go about assessing the percent hybridity. Appellants provided an example of one method by which one would go about determining the percent hybridity using molecular markers. Determining the percent hybridity is routinely used in plant breeding and is well within the ability of one of ordinary skill in the art. Appellants note the Examiner has acknowledged as much with respect to at least morphological markers in the 3-15-2002 Office Action at page 15, third paragraph: "Sun et al. teach in Table II the determination of the hybridity of the open pollination step."

With respect to determining the percent hybridity using molecular markers, the specification provides ample guidance to the skilled artisan, at least in the form of a working example. At page 10 of the specification, Appellants describe assessing the hybridity of the hybrid DS9705Hyb by selfing plants of the parental lines B209, DS9671, C580, and Thor to generate pure S1 seed, and isolating DNA from plants grown from the S1 seed for subsequent analysis. The Example at page 10 (and sequence listing for SEQ ID NOS: 1-4) further provides sequences for four primers used to determine the hybridity of plants grown from DS9750Hyb seed.

Despite the Examiner's unsupported argument to the contrary (see, e.g., Advisory Action at page 2), one of skill in the art would appreciate that in order to evaluate hybridity using molecular markers, one compares the characteristics of plants grown from a crossing with those

of the parental components. The specification, at least by way of example, provides additional guidance with respect to a method of determining hybridity that is routinely practiced by skilled artisans without undue experimentation.

Therefore, Appellants respectfully assert that the claims of Group IV, in light of the level of skill in the art and guidance presented in the specification, are fully enabled.

Rejection of Claims 1-4 Under 35 U.S.C. § 102(b)/ §103

Groups I and II

The Examiner has maintained the rejection of claims 1-4 as anticipated over Northrup et al. Claims 2-4 stand rejected as anticipated by, or in the alternative, as obvious over Northrup et al. and Thompson et al.

Northrup et al. teach that Thor is a synthetic variety. Thompson et al. teach the development of an unrelated synthetic variety named "Syn C."

Thus, the rejections stem from the Examiner's continued insistence that the claimed invention is developed using the synthetic variety Thor rather than a selected line of Thor, a proposition that Appellants continue to strenuously dispute, as discussed above. As noted, the Examiner has interpreted the names A833, B209, C580, DS9761 and Thor as being designations for synthetic populations or varieties, despite evidence to the contrary presented during prosecution and in the Declaration of Dr. Paul Sun at paragraph 9:

As one skilled in the art, it is my opinion that the application clearly describes that the seed identified by Accession Number PTA-2759 was obtained by crossing cytoplasmic male sterile hybrid plants with select clones or plant lines, rather than with a synthetic variety.

As Appellants have described in the specification and explained above, the pollenizer plants used as parental components to produce the seed of claim 1 were selected on the basis of desirable agronomic characteristics and selfed or interpollinated to obtain breeder and foundation seed. These select clones are distinct from grown from synthetic varietal seed. A833 is a cytoplasmic male sterile line and B209 is a maintainer line, each of which was selected as described in the specification. Appellants respectfully submit that none of the plants obtainable by growing the seed of claim 1 is identical to plants grown from synthetic varietal seed of Thor.

The Examiner's citation of *In re Thorpe* regarding product-by-process claims is inapposite. The Application does not include product-by-process claims. Moreover, as asserted above, the "product," which Appellants take to mean the claimed seeds of Group I and claimed plants of Group II, are not identical in any respect to the seeds or plants taught in either of Northrup et al. or Thompson et al., inherently or otherwise.

Rejections Under 35 U.S.C. §103

Groups III and IV

The Examiner has maintained the rejection of claims 5-6 and 9 as obvious over Sun et al. Claims 5-7 stand rejected as obvious over Sun et al. in view of Viands et al. Claims 5 and 8 stand rejected as obvious over Sun et al. in view of Rotili et al., in further view of Vos et al.

The Examiner asserts that Sun et al. (US Patent No. 4,045,912) teaches a method of making alfalfa seed with 76.3 or 85% hybridity using a ratio of 3:1 male sterile to male fertile seed. The Examiner also asserts that Sun et al. teach increases in the percent hybridity obtained with increasing ratios of male sterile to male fertile alfalfa plants. The Examiner concludes that it would have been "an obvious design choice by one of ordinary skill in the art to utilize the

method for producing a synthetic variety taught by Sun et al. and modify the ratio of pollenizers from the 3:1 ratio taught by Sun et al., ... to design a method with a 4:1 ratio which could make alfalfa plant with at least an 85% increase in seed yield as broadly claimed."

Appellants respectfully submit that the Examiner has failed to establish a prima facie case of obviousness, which requires: (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) a reasonable expectation of success; and (3) the art reference or combination of references must teach all of the claim limitations (MPEP 2142). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (MPEP 2143).

Appellants assert that: (1) all of the claim limitations are not taught or suggested by the references; (2) there is no suggestion to modify or combine the cited art to arrive at the claimed invention: (3) there is no reasonable expectation of success; and (4) the primary reference actually teaches away from the claimed invention, as is detailed below.

(1) Claim Limitations Not Taught or Suggested

As the Examiner has acknowledged, Sun et al. does not teach or suggest practicing a method of producing alfalfa seed having at least 75% hybridity comprising crossing male sterile hybrid alfalfa by male fertile alfalfa plants planted in a ratio of about 4:1, as required by independent claim 5 and its dependent claims 6-9. None of the secondary references teach a planting ratio of 4:1.

(2) No Suggestion To Modify or Combine Cited Art

Sun et al. provides no motivation to increase the planting ratio. Sun et al. teaches that maximum seed yield is obtained by planting male sterile and male fertile plants in a ratio of 1:1 to 3:1, and that these ratios <u>must</u> be used. Col. 3, lines 13-16 (emphasis added). The Examiner maintains however, that a select portion of Table II, i.e., Replicate II, teaches a general trend of increased hybridity from increasing planting ratios. What the Examiner ignores, however, is that Table II, in the column titled "Average of 2 Replicates," (which is more appropriately used to interpret the data presented) further demonstrates that decreased seed yield also results from increasing planting ratios. For example, in the upper group of data in the "wt./pl." column, as the ratio increases from 1:1 to 2:1 to 3:1, the seed yield decreases from 59.9 to 46.6 to 38.9, respectively. Thus, one of skill in the art would understand from both Table II and the text of Sun et al. that in order to optimize both seed yield and hybridity, the planting ratio must remain within the stated range of 3:1 to 1:1. Therefore, Sun et al. provides no suggestion to modify the ratio to arrive at the claimed invention, requiring a planting ratio of 4:1. None of the secondary references cure this deficiency.

(3) No Expectation of Success

Similarly, Sun et al. provides no reasonable expectation of success in a modified planting ratio. As noted above, the data presented in Table II suggest that the achieving the optimum balance between seed yield and hybridity requires that the planting ratio remain within the stated range of 1:1 to 3:1. Thus, one of skill in the art would not expect success in the utilization of any increased planting ratio, much less the claimed ratio of 4:1.

(4) Clear Teaching Away From Claimed Invention

Finally, Sun et al. teaches away from increasing the ratio of male sterile to male fertile plants to any ratio greater than 3:1. Sun et al. teaches that male sterile alfalfa have reduced seed yield relative to male fertile alfalfa (column 1, lines 34-37), and that in order to obtain maximum seed production, "the ratio of male sterile to male fertile alfalfa plants must be in the range of 1:1 to 3:1" (column 3, lines 13-17, emphasis added). Thus, in the face of this teaching, one of skill in the art would be discouraged from altering the ratios taught. Proceeding contrary to the accepted wisdom in the art is evidence of non-obviousness. MPEP 2145. None of Viands, Rotili or Vos cure the deficiencies of Sun et al. by teaching or suggesting the claimed ratio.

The Examiner further maintains that the Appellants have not demonstrated any advantage in using a planting ratio of 4:1 and that the increase in the planting ratio over that used in Sun et al. does not provide unexpected results. However, Appellants respectfully assert that it is the Office's initial burden to demonstrate *prima facie* obviousness, not Appellants' burden to demonstrate unexpected results in the first instance. MPEP 2142.

As demonstrated above, the Examiner has not established obviousness of the claimed invention over any of Sun et al., Viands et al., Rotili et al., Vos et al., or any combination thereof. Appellants are not therefore required to show unexpected results to establish non-obviousness of the presently claimed invention. To the contrary, because all claimed elements are not taught by the cited art, because there is no motivation to combine the cited art, because there is no expectation of success and because the primary reference clearly teaches away from the presently claimed invention, Appellants assert that the claims of Groups III and IV are not obvious over the cited art. Therefore, withdrawal of the rejections is respectfully requested.

Conclusion

In view of the foregoing, reversal of the final rejection of claims 1-9 and allowance of claims 1-9 are respectfully requested.

Respectfully submitted,

Billie Jean Smith Reg. No. 36,940

File No. 087165-9051-00

Michael Best & Friedrich LLP 100 East Wisconsin Avenue Milwaukee, Wisconsin 53202-4108

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APPENDIX

LISTING OF CLAIMS

This Listing of Claims will replace all prior versions of claims in the application.

Claim 1 (Previously presented): A *Medicago sativa* or cultivated alfalfa seed deposited as ATCC Accession Number PTA-2759.

Claim 2 (Previously presented): A *Medicago sativa* hybrid or cultivated alfalfa plant that is grown directly from the seed deposited as ATCC Accession Number PTA-2759, or a plant grown from a vegetative cutting, callus or tissue culture obtained from a plant part grown from the seed deposited as ATCC Accession Number PTA-2759, or a clonal plant thereof.

Claim 3 (Original): Pollen from the plant of claim 2.

Claim 4 (Original): An ovule from the plant of claim 2.

Claim 5 (Previously presented): A method of producing alfalfa seeds having at least 75% hybridity comprising the steps of:

- (a) crossing by controlled pollination cytoplasmic male sterile alfalfa plants with maintainer line alfalfa plants to produce cytoplasmic male sterile hybrid plants;
- (b) selectively harvesting seed from the cytoplasmic male sterile hybrid plants of step (a);

- (c) crossing male sterile hybrid alfalfa plants by male fertile alfalfa plants by allowing open pollination of plants grown from the seed of step (b) and seed from at least one line of male fertile alfalfa plants, the male sterile seed and male fertile seed planted at a ratio of about 4:1; and
 - (d) non-selectively recovering the seeds from the pollinated alfalfa plants of step (c).

Claim 6 (Original): The method of claim 5, further comprising the step of determining the hybridity of the progeny of the crossing.

Claim 7 (Previously presented): The method of claim 6, wherein the step of determining the hybridity of the progeny of the crossing is with a genetic or morphological marker.

Claim 8 (Previously presented): The method of claim 6, wherein the step of determining the hybridity is accomplished with amplified fragment length polymorphism analysis.

Claim 9 (Previously presented): The method of claim 5, wherein the average seed yield of step (d) is at least 80% of the average seed yield obtainable by selfing the male fertile plants of step (c).

Claim 10 (Cancelled)

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant(s): Sun, et al.

Docket No.:

87165/9051

Serial No.:

09/773,976

Group Art Unit:

Filing Date: January 31, 2001

Examiner:

Francis P. Moonan

Confirmation No.: 6280

Title:

ALFALFA HYBRIDS HAVING AT LEAST 75% HYBRIDITY

DECLARATION OF PAUL SUN UNDER 37 CFR § 1.132

Assistant Commissioner for Patents Washington, DC 20231

Sir:

I, Paul Sun, do hereby declare and state the following:

- 1. I am a co-inventor of the subject matter of the above-cited application.
- I am employed as Vice President of Research at Dairyland Seed, Clinton, WI, where I 2. have worked since since 1981.
- I received my Ph.D. in Plant Breeding and Genetics from the University of 3. Wisconsin-Madison in 1969. This Declaration is accompanied by my curriculam vitae, attached as Appendix A.
- I have reviewed the Office Action dated March 15, 2002 (hereinafter, "the Office 4. Action") and the references cited therein.
- Claims 1-10 of the present invention are rejected under 35 U.S.C. 112, first paragraph as not being enabled by Applicants' disclosure. The Examiner stated that claim 1 is drawn to any Medicago sativa or cultivated alfalfa seed derived with the synthetic variety Thor, based on Applicants' description at page 2, lines 6-10, which the Examiner characterized as "describing to one of skill in the art a plant made with a series of alfalfa plants with arbitrary names and a population of genetically segregating alfalfa plants comprising the synthetic variety Thor." Based on his assessment of what one of skill in the art would understand from the disclosure, the Examiner broadly interpreted the names DS9705Hyb, A833, B209, DS9761, and C580 as "synthetic varieties".

- 6. The alfalfa seed deposited with the ATCC on December 4, 2000 and identified by Accession Number PTA-2759 was made by crossing a selected cytoplasmic male sterile alfalfa plant (A833) with a selected maintainer line (B209) by controlled pollination and selectively harvesting seed from the cytoplasmic male sterile plant to produce cytoplasmic male sterile hybrid seed (A833xB209). Plants grown from seed of A833xB209 cytoplasmic male sterile hybrid were crossed by open pollination with plants grown from seed from selected alfalfa male fertile clones which are designated Thor, DS9671 and C580. These selected clones were selected on the basis of agronomically desired properties such as: forage yield, forage quality, persistence, disease, insect and nematode resistance.
- 7. Applicants referred to the specific parental components ((A833xB209), Thor, DS9671, and C580) of the hybrid seed identified by Accession Number PTA-2759 as selected clones or plant lines. One of ordinary skill in the art would understand that a plant clone is a group of plants originated by vegetative propagation from a single plant, and that a plant line is a group of individuals from a common ancestry, which is narrower than a strain or variety.
- 8. I participated in the preparation of the patent application, and reviewed and approved the application that was filed with the United States Patent and Trademark Office on January 31, 2001. At the time the application was filed, it was my opinion that the application clearly described the method by which the seed deposited as identified by Accession Number PTA-2759 was obtained, specifically, by crossing cytoplasmic male sterile hybrid plants with select clones or plant lines, rather than with a synthetic variety.
- 9. I have reviewed the application in light of the Examiner's rejection of the claims on the basis of lack of enablement. As one skilled in the art, it is my opinion that the application clearly describes that the seed identified identified by Accession Number PTA-2759 was obtained by crossing cytoplasmic male sterile hybrid plants with select clones or plant lines, rather than with a synthetic variety.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 9/6, 200 2.

Paul Sun

Curriculum Vitae of Paul Sun

Education: 1957 B.S. Taiwan Agriculture College

1967: M.S. University of Wisconsin

1969: PH.D University of Wisconsin (Agronomy Dept)

Dissertation Title: Inheritance of Kernel Weight of six spring wheat crosses

Work Experience:

1969-1975: Alfalfa Breeder

Teweles Seed Company Clinton, WI 53525

Applied the concept of general combining ability and convergence of germplasm to alfalfa breeding and developed Magnum alfalfa which made 10% genetic gain in compare check variety Vernal in 1976.

1976-1980: Soybean Breeder

Pfizer Genetics Beaman, IA

Developed 5 commercially useful soybean varieties: CX155, CX276, CS290, CX297, CX380.

1981-2002: Research Director

Dairyland Seed Co., Inc. Clinton, WI 53525

Work on Hybrid Alfalfa, soybeans and Hybrid Com. In 1985, developed DSR317 soybean variety which made 5% genetic gain compared to the best mid 3 maturity soybean. DSR317 was on the market for 10 years. There are about 7 million bags of DSR317 and sister lines that were grown by farmers.

Patentee:

U.S. Patent No. 4,045,912

Issue Date: September 6, 1977

Title: PRODUCTION OF ALFALFA SEEDS

U.S. Patent No. 5,724,767 Issue Date: March 10, 1998

Title: ALFALFA PRODUCTS AND METHOD FOR PRODUCING

ALFALFA PRODUCTS FOR A SEQUENTIAL SYSTEM

U.S. Patent No. 6,051,759 Issue Date: April 18, 2000

Title: ALFALFA PRODUCTS AND METHOD FOR PRODUCING

ALFALFA PRODUCTS FOR A SEQUENTIAL

HARVESTING SYSTEM

U.S. Patent No. 6,359,199 Issue Date: March 18, 2002

Title: ALFALFA PRODUCTS AND METHOD FOR PRODUCING

ALFALFA PRODUCTS FOR A SEQUENTIAL

HARVESTING SYSTEM

Advisor:

1993 Sent by the United Nations to China for corn breeding advisor.

Visited five research stations, giving 12 lectures on corn breeding.

Publications: Inheritance of Kernel weight for six spring wheat crosses: Crop Sciences, 1971.

Co author on the Chapter of Pollination Control, Mechanical and Sterility of Agronomy NO. 29, Alfalfa and Alfalfa Improvement, Edited by A.A. Hanson,

D. K. Barnes and R.R. Hill, Jr., ASA, CSSA and SA, 1988.

X:\CLIENTB\087165\9051\B0167043.1

LEXSEE 1992 PAT APP LEXIS 35

Ex parte * * *

Appeal No. 92-0393 from Art Unit 1804.

Application for Patent Novel Soybean Variety * * *

Board of Patent Appeals and Interferences

1992 Pat. App. LEXIS 35; 27 U.S.P.Q.2D (BNA) 1492

September 28, 1992, Decided

[*1]

Before Goldstein, Goolkasian, McCandlish, Lynch and J. Smith, Examiners-in-Chief.

COUNSEL:

* * * et al. for appellant.

Supervisory Patent Examiner - Elizabeth C. Weimar

Examiner - P. Rhodes

OPINIONBY: GOOLKASIAN

OPINION:

Goolkasian, Examiner-in-Chief.

This is an appeal from the examiner's final rejection of claims 5 through 8, which are all the claims remaining in the application.

Claims 5 through 8 read as follows:

- 5. A method of producing * * * comprising self-pollinating an * * * soybean plant.
- 6. A soybean plant designated * * *
- 7. Seed, which upon germination produces the plant of claim 6.
- 8. Seed produced by the plant of claim 6.

The references relied on by the examiner are:

Russell, Studies In The Agricultural And Food Sciences, "Plant Breeding for Pest and Disease Resistance," Butterworths Press, 1978, pages 36-41.

SNB 112 Germplasm Resources Information Network release date of cultivar Pella 1979.

Keeling, Plant Disease, "A New Physiologic Rase of Phytophthora megasperma f. sp. glycinea," Vol. 68, No. 7, 1984, pages 626-627.

Athow, World Soybean Research Conference III, "Phytophithora Root Rot Of Soybean," Westview Press, 1985, pages 575-581.

PI 88447 Germplasm Resources [*2] Information Network, date available from USDA-ARS soybean collection 1986.

This invention concerns a novel variety of soybean plant, seeds produced therefrom, and a method of producing the seeds by self-pollinating the soybean plant. The novel variety, named * * *, was developed by appellant and is a cross between a commercial soybean known as * * * and a known variety available from Iowa State University and identified in the specification as 'Pella.'

Appellant seeks utility patent protection under 35 U.S.C. § 101. n1 Appellant's assignee, a seed producer, considers utility patent protection more desirable than protection under the Plant Variety Protection Act (PVP) because the PVP has a loophole therein known as the "farmer's exemption" which allows farmers to save and sell seeds in competition with the developer of the novel variety.

n1 The patentability of plants and seeds under 35 U.S.C. § 101 has been confirmed by this Board in Exparte Hibberd, 227 USPQ 443 (BPAI 1985).

Appellant's specification does not follow the standard format set forth in section 608.01(a) of the Manual of Patent Examining Procedure (M.P.E.P.). The specification is somewhat cryptic and [*3] provides little more detail than would be provided in a specification submitted to the Department of Agriculture under the Plant Variety Protection Act. There is no section therein explaining "the nature and gist of the invention or the inventive concept." (See the suggestion set forth in M.P.E.P. § 608.01(a), Form Paragraph 6.02). Importantly, the specification has little specific language which distinguishes the claimed soybean variety from other soybean varieties and does not explain the significance of any differences in attributes between the novel variety and varieties that are old in the art. See 37 CFR § 1.71 (b). n2

n2 37 CFR 1.71(b) reads as follows:

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

A problem has arisen during prosecution because, [*4] not knowing the nature and gist of the invention and what appellant regards as the inventive concept, the examiner has had considerable difficulty examining the application, especially with regard to formulating a conclusion of obviousness. On this point, the examiner notes that while appellant's soybean variety is a cross between two different varieties, appellant's specification does not advise the reader as to (1) the characteristics possessed by each parent variety, (2) which of these characteristics were expected to be passed on to progeny plants, and (3) what inheritable characteristics (goals) were sought in the progeny. The examiner also complains that the specification does not reveal what important characteristics were needed, but lacking, in prior varieties of soybeans and whether the claimed crossbreed (hybrid) fulfilled the need. In other words, the examiner is of the opinion that the instant specification lacks the specific technological "background" information necessary for the examiner to assess whether or not the claimed invention meets the statutory prerequisites for the grant of a patent.

Appellant's specification has been "objected to" by the examiner [*5] because, in her words, the specification fails "to provide (a) full written description, and (b) enablement and best mode of practicing the claimed invention." The claims are also "rejected" under 35 U.S.C. § 112, first paragraph, for the same reasons.

There are significant legal and procedural distinctions between an "objection" and a "rejection." An "objection" to the specification indicates that the specification is not satisfactory to the examiner because it does not conform to certain criteria established by (a) the patent statute, (b) the Patent and Trademark Office rules of practice, or (c) conventions and customary practices which have evolved over the years. A "rejection" constitutes an adverse decision by the examiner denying the grant of a patent for the subject matter claimed on the ground that the invention as set forth in the claims does not meet the requirements imposed by Congress in the patent statute.

In this case, that part of the examiner's "objection" which centers on description, enablement and best mode concerns the correspondence of the specification to the statutory requirements set forth in 35 U.S.C. § 112 and is within the jurisdiction of this Board. [*6] However, that part of the "objection" which relates to the examiner's desire for

information concerning (a) an explanation of the "gist" of the invention, (b) the phenotypic characteristics of the parent plants and the inheritability thereof, and (c) the goals sought to be achieved by the inventors, relates solely to the ease and accuracy of the examination process and the ability of the examiner to obtain sufficient information therefrom to effectively examine the application. It concerns either the rules of practice or established customs and practices. It is outside the jurisdiction of this Board. n3

n3 35 U.S.C. § 134, which provides the right of appeal, refers only to the appeal of rejections of claims and, accordingly, restricts the jurisdiction of the Board of Patent Appeals and Interferences to considering the propriety of "rejections." The propriety of "objections" and other procedural requirements is solely within the jurisdiction of the Commissioner of Patents. In re Hengehold, 440 F.2d 1395, 169 USPQ 473 (CCPA 1971). See also In re Haas, 486 F.2d 1053, 179 USPQ 623 (CCPA 1973) regarding "objections" which are de facto rejections.

When the specification [*7] is "objected to" and the claims are "rejected" for the same reasons, consideration of the propriety of the objection is usually held in abeyance because the Board's decision may well be dispositive of both the "objection" and the "rejection." "New Matter" questions often fall into this category. In this instance, however, the examiner's "objection" and "rejection" cover somewhat different territory and our decision with regard to the examiner's "rejections" may not be dispositive of all "objections."

ENABLEMENT

We consider first the examiner's rejection under 35 U.S.C. § 112, first paragraph. It is the examiner's position that the claims are based on a disclosure which does not enable one skilled in the art to make the claimed * * * variety of soybean plant and seeds and does not set forth the best mode of carrying out the invention. More specifically, it is the examiner's position that the description of "how to make" the invention by crossing two varieties omits significant information concerning the breeding process, the selection pressures for disease resistance, the methods of measuring and testing resistance, etc. In the examiner's opinion, one of ordinary [*8] skill in the art could not independently develop the * * * plant and seed claimed herein following the general procedures set forth in the specification.

Appellant urges that even if exacting directions for crossbreeding and selection were detailed, one could not follow the directions to obtain the same * * * variety but, rather, would arrive at a substantially similar but yet different variety of plant. Appellant has offered to deposit seeds of the * * * soybean variety in the American Type Culture Collection (ATCC), a public depository recognized by the United States Patent and Trademark Office. Appellant urges that planting the deposited seed is the best mode of making new plants and seed.

There is no question that one having * * * seeds available through the ATCC depository would be enabled to grow a * * * plant and produce additional seeds therefrom. The procedure to be used by appellant to deposit seeds of the plant does not differ from that used to deposit a culture of microorganism as sanctioned by the Court of Customs and Patent Appeals in In re Argoudelis, 434 F.2d 1390, 168 USPQ 99 (CCPA 1970) and accepted by the Patent and Trademark Office in Section 608.01(p) [*9] of the M.P.E.P. as an alternative procedure for meeting the requirements of 35 U.S.C. § 112 for "biological material". We see little difference between the concept of screening a microorganism to develop a desired strain, which was before the court in Argoudelis, and the concept of screening plants to develop a desired variety which is before us now. Appellant has disclosed the parent varieties crossed and provided a general description of the selection process. An exacting description relating to how to select for the desired plant could only detail an experimental screening program which would not necessarily result in the exact same plant being obtained but, rather, would result in one which, though different, would have virtually the same characteristics. We are in agreement with appellant that upon deposit of the seeds in the ATCC the specification satisfies the enablement and best mode requirements of 35 U.S.C. § 112.

DESCRIPTION

We consider next the examiner's rejection under 35 U.S.C. § 112 for lack of description. This rejection has two aspects. In its first aspect, the examiner notes that certain language used by appellant to describe the plant variety is [*10] considered as inherently so indefinite that one skilled in the art is unable to identify the plant variety and distinguish it from other species. The particular language of concern relates to (a) the plant variety's susceptibility to disease, (b) its peroxidase content, and (c) its allegedly "superior yield."

The examiner's concern with the language of the specification cannot serve to substantiate the rejection of the claims under the first paragraph of 35 U.S.C. § 112. Appellant's specification sets forth a reasonable description of the characteristics of the seed and plant including, flower color, plant type, maturity group, bacterial resistance, nematode resistance, etc. The specification also names the parent plants used to obtain the claimed cross. As noted by appellant on pages 3 and 4 of the Reply Brief, there is sufficient information of record to establish that the language objected to is accepted by the art as descriptive of the characteristics of a soybean variety. We reverse with regard to this first aspect of the rejection under 35 U.S.C. § 112.

In its second aspect, the examiner asserts that the written description set forth in the specification fails to adequately [*11] describe the invention or breeding goals in terms that make the invention searchable as a whole. The examiner states unequivocally that she would want to know additional information concerning each of the parent varieties which were crossed to obtain the claimed plant. She indicates that traits which were known features of the parent lines directly relate to the obviousness issue because many of these traits may well be expected to occur in the progeny. The examiner wishes to be apprised of the selection procedure used by appellant because she wants to know whether the particular traits or characteristics of the claimed variety were expectations based on known characteristics of the parents or fortuitous variations observed in a selection procedure designed to select for something other than what was achieved. The examiner also wants to know why the varieties 'Pella' or 'Pella 86' are considered by appellant to be closest to that claimed. In other words, the examiner's concern is that appellant's specification does not serve to distinguish the invention from other things before known and used such that a proper examination and consideration of the obviousness issue may be [*12] made.

Appellant urges, on the other hand, that a disclosure must be considered adequate if it meets the requirements of 35 U.S.C. § 112. Appellant urges, "[T]here is no requirement that an application must be drafted in order that an Examiner can formulate a search" (Reply Brief, page 2).

We are in agreement with appellant that there is nothing in 35 U.S.C. § 112 which supports a rejection on the ground that the specification does not provide enough information for the examiner to formulate a search and examine the application.

The examiner has pointed to no case law which indicates that a disclosure which describes an invention and enables the practice of that invention in accord with 35 U.S.C. § 112, in this case by depositing in a public depository the seed necessary for the practice of the invention, must also include additional information to assist in the examination process and make easier the examiner's search and patentability determination. The claimed soybean is described in the specification to the extent that there is no question that appellant was in possession of the invention as of the time the instant application was filed. Because seed is to be deposited [*13] in a public depository, the specification is enabling and sets forth the best mode of carrying out the invention. While the examiner may want to possess additional information regarding the inventive process, in this case the inheritable characteristics of parent species of plants and the particular procedure used to select for the claimed plant, in order to carry out a thorough examination, there is nothing in the statute which commands its inclusion in the specification.

There is no question, however, that the description, enablement, and best mode requirements of 35 U.S.C. § 112 are but the bare minimum mandated by the statute and "are not the maximum that can be demanded in an application." In re Davies, 475 F.2d 667, 177 USPQ 381, 385 (CCPA 1973). As stated by the court of Customs and Patent Appeals in In re Argoudelis, supra, 434 F.2d 1393, 168 USPQ at 102, the disclosure of a patent application must not only be sufficient "to preclude the possibility that a patent could issue without any person skilled in the art being thenceforth enabled to make and use the invention," but also must be sufficient "to permit a thorough examination by the Patent [and Trademark] Office." [*14] n4 (We note, for example, that the Patent and Trademark Office rule which relates to the deposit of biological materials specifically requires the specification to include sufficient description of the deposited material not only to specifically identify it but also "to permit examination.") n5

n4 See also Judge Baldwin's concurring opinion in Argoudelis, supra, 434 F.2d at 1395, 168 USPQ at 104, wherein it is stated:

Practical necessity, of course, requires that an application disclosure be intelligible and capable of evaluation *before* the issue date. The examining bodies of the Patent Office must be able to understand what a claimed invention is, how it works, what utility it might possess, before they can adequately determine whether such invention merits the grant of a patent.

n5 37 CFR § 1.809(d) (3) reads as follows:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
- (1)...;
- $(2) \dots;$
- (3) a description of the deposited biological material sufficient to specifically identify it and to permit examination.
 - (4)...;

Though there is nothing in the patent statutes which mandates inclusion in the specification of information [*15] which the examiner considers important (a) with regard to distinguishing the claimed invention from other inventions and from what is old, and (b) with regard to whether to allow the application to issue as a patent, there is nothing in the patent statutes which precludes the examiner's requiring such information be included. Such a requirement, however, must be made by way of "objection" and is not within the jurisdiction of this Board. Because it is outside our jurisdiction, we reverse pro forma that aspect of the rejection under 35 U.S.C. § 112 (first paragraph) which pertains to the searchability of the invention described in the specification.

OBVIOUSNESS

Claims 5 through 8 stand rejected under 35 U.S.C. § 103 as obvious over the soybean varieties described in the documents identified as GRIN accession numbers SNB112 ('Pella') or P188447 (Chinese soybean), each in view of the combined teachings of Athow, Russell and Keeling. It is the examiner's position that although the prior art 'Pella' and Chinese soybean plants differ from the claimed plant in pod color, pubescence color and *Phythophthora* root rot resistance, the claimed invention would has been obvious, [*16] nevertheless, because (a) the color differences fall within the known range of variation for the soybean species, and (b) the secondary references make obvious the breeding of *Phythophthora* rot resistance into the plants.

We have carefully considered all of appellant's arguments but, nevertheless, are unpersuaded of error in the examiner's basic position and, accordingly, we affirm the rejection.

The claimed plant does not appear to differ significantly from the prior art plants as measured by numerous characteristics. Both the claimed plant and the prior art plant, SNB112 ('Pella'), are similar in color. Each has purple flowers and yellow seeds. 'Pella' has tan pod color versus brown pod color for the claimed plant. Both plants differ slightly in pubescence color and hila color, but both belong to maturity group III and has approximately the same oil yield. The Chinese soybean plant is even more similar in color and has similar oil yield and protein content.

As noted by the examiner, the secondary references teach that it is well known to breed root rot resistance into a plant by crossing the plant with other varieties having resistance to root rot. Accordingly, we are [*17] in complete agreement with the examiner that it would have been obvious to modify the soybean varieties of the primary references in order to impart root rot resistance to the plants. That this is so is evidenced by an admission made by appellant in the Petition to the Commissioner dated January 22, 1991, wherein appellant advises that the soybean variety 'Pella 86' is a version of 'Pella' having rot resistance conferred thereto using back crossing techniques in association with non-resistant 'Pella' and, necessarily, a variety having root rot resistance.

Appellant urges that the declaration of * * * reveals that the claimed variety is unobvious because it outyields 'Pella 86' and is "shorter than 'Pella 86'" and more resistant to brown stem rot and to charcoal rot.

We have reviewed the data and the declaration but are unpersuaded of patentability because there is nothing of record which explains why the differences between the claimed variety and a rot resistant variety such as 'Pella 86' are so significant and unexpected that they should weigh more heavily than the numerous similarities between the claimed variety and the varieties of the cited prior art.

We remind appellant [*18] that in submitting evidence asserted to establish differences and/or unobvious results sufficient to dissipate a prima facie case of obviousness, there is a burden on the patent applicant to establish not only that the differences in results achieved are in fact "unexpected and unobvious" but also to establish that the differences are of practical significance. See In re Merck, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Klosak, 455 F.2d 1077, 173 USPQ 14 (CCPA 1972); In re D'Ancicco, 439

F.2d 1244, 169 USPQ 303 (CCPA 1971) and In re Freeman, 573 F.2d 1237, 197 USPQ 464 (CCPA 1978). See also the recent decision of this Board in Ex parte Gelles, 22 USPQ2d 1318 (BPAI 1992).

We note, for instance, that it may not be unexpected that the claimed cross is shorter than 'Pella 86.' It must be borne in mind that root rot resistance was introduced into the claimed variety by breeding 'Pella' with * * * The materials submitted by appellant on March 26, 1990 include a plant variety protection application for * * * describing it as a variety specifically bred for its rot resistance. The data therein [*19] indicates that the plant height of * * * is only 71 cm. It is not necessarily unexpected that the breeding of 'Pella' with the shorter variety * * * would not only impart rot resistance but also result in shorter progeny.

With regard to the rejection over Chinese soybean, appellant urges that there is a difference in the flowering and maturity dates but presents no evidence on this point. It is well settled that in order to overcome a prima facie case of obviousness, there is a necessity for "clear and convincing evidence" of unobvious results. In re Lohr, 458 F.2d 1013, 137 USPQ 548 (CCPA 1963). Counsel's unsupported arguments and allegations cannot take the place of that evidence. In re Greenfield, 571 F.2d 1185, 197 USPQ 227 (CCPA 1978).

We has carefully reviewed appellant's specification and find nothing therein which establishes a base for judging whether the differences asserted by appellant are, in fact, significant and unexpected. The specification says nothing regarding the significance and relative importance of such criteria as maturity date, shortness of plant, flower color and flowering date. The specification offers nothing regarding whether or not [*20] each parent variety crossed to develop the claimed variety was possessed of desirable characteristics or, alternatively, known to have recessive genes for the desirable characteristics, which genes would be expressed in the progeny upon crossing. Accordingly, we are unable to ascertain whether or not the particular features attributed to the claimed *** variety and relied on by appellant for patentability are sufficiently significant and unexpected to dissipate the examiner's *prima facie* case.

In a somewhat analogous situation, the Court of Customs and Patent Appeals in *In re Davies*, 475 F.2d 667, 177 USPQ 381 (CCPA 1973) noted that "the public will derive the most benefit from a patent when it discloses on its face those properties or utilitarian advantages which were ultimately persuasive on the question of nonobviousness" (emphasis added). In the case before us, appellant's specification places no more emphasis on shortness of plant and bacterial resistance than on flowering date, flower color or hila color. Absent an explanation of relative significance in either the specification or the submitted declaration, it is virtually impossible for the decision maker [*21] to conclude that the dissimilarities argued by appellant outweigh the similarities proffered by the references.

Claim 5, which is directed to the specific process of producing * * * seed by "self-pollinating" * * * soybean plant, has been separately rejected as directed to a pollination process which, albeit performed by novel soybeans, was well-known in the art and in use long before the instant invention was made. The examiner relies on *In re Durden, 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985)* and has taken the position that despite the novelty of the plant and the seed, the claimed process is an old one and, accordingly, is unpatentable.

Appellant urges that the claimed process is "a process of using" a new variety of soybean plant and is patentable as a "process of using" under the rule espoused in *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990) and *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974). This argument has been countered by the examiner who notes that the preamble of claim 5 designates the process as a "method of producing," i.e., "making" seeds.

We affirm the examiner's rejection. For reasons set forth above, we are in [*22] agreement with the examiner that the claimed * * * variety of plant and, accordingly, the claimed process inherent in the ordinary use of that plant, would have been obvious to one of ordinary skill in the art at the time the invention was made.

PUBLIC USE OR ON SALE

Claims 5 through 8 stand rejected under 35 U.S.C. § 102(b) on the grounds that the invention was "in public use," or "on sale," more than one year prior to the filing of the instant application.

The "public use or on sale" rejection was engendered by an Information Disclosure letter submitted by appellant on June 25, 1990 (Paper No. 7). This letter advised the examiner that it is standard practice in the soybean art to transfer seedstock of a new plant variety to "growers" who are paid a fee to plant the seedstock and increase the inventory of seed available for sale when the new variety of seed is announced via publication in a seed catalog. The letter also advises that the growers pay applicants' assignee a fee for use of the seed and the grower returns all the harvested seed for subsequent sale to farmers. The Information Disclosure letter indicates that applicants' assignee retains title to all seed produced [*23] by the grower, the grower returns all the harvested seed to the assignee and the grower, by

contract, does not have the right to sell, dispose of, use or otherwise encumber the seed or permit another to sell, dispose of, use or otherwise encumber the seed. A copy of a blank contract was attached to the Information Disclosure letter.

The examiner's rejection has two aspects, "public use" and "on sale." We consider first the "on sale" aspect of the rejection. We affirm the examiner's rejection noting that there are clauses in the contract which trigger the "on sale" bar.

Clause 1, on the back of the blank contract, indicates that title to the seed does not normally vest in the grower and that applicants' assignee remains the owner of the seed and the crop produced therefrom. Because title does not leave the assignee and does not vest in the grower, it would appear that Clause 1 negates interpretation of the contract as one of "sale." As noted by the examiner, however, there are certain unnumbered paragraphs of the contract relating to "quality" and "acceptance and payment" which contain special provisions (conditions) therein which, if activated, cause title to vest immediately [*24] in the grower. Accordingly, because the grower has paid for the seed, a sale may be accomplished under the contract when and if the special contract provisions are activated. The contract may properly be viewed as one of "conditional sale."

More specifically, the contract has an "acceptance and payment" clause which has a blank space therein which sets the percentage of the "growers contracted production" of soybeans which will be accepted by the company. Any amount of total production not accepted by the company is deemed "rejected for seed use" such that the terms of paragraph 8 apply to that seed. Paragraph 8 specifically states that title to "rejected seed" immediately vests in the grower and the rejected seed constitutes the growers entire compensation thereunder. Should the blank of the acceptance and payment clause be filled in with any number less than 100%, an actual sale would occur as of the date the contract is entered into because a predetermined quantity of "rejected seed" may be considered as constituting payment for the growers' services. The grower has the right to use rejected seed for purposes other than planting.

The soybean contract also includes a "quality" [*25] clause which indicates that the company is not obligated to accept any portion of the contracted production which does not comply with the quality standards established regarding moisture content, "clean out" and germination, or is denied "certification" for any reason. The "quality" clause establishes conditions which relieve the company of obligation to accept any portion of the contracted production as seed. Necessarily, that portion not accepted will be considered "rejected" seed covered by clause 8 of the contract. Title to said rejected seed vests immediately in the grower. We are in agreement with the examiner that should the "quality" clause be activated, the contract would clearly evidence a sale. More importantly, during the life of the contract the assignee was never obligated to accept rejected seed, and at all times during performance of the contract there was a distinct possibility that title could change hands. This is sufficient to trigger the "on sale" bar. no 35 U.S.C. § 102(b) does not require an actual sale but only that the material be "on sale." We affirm the examiner's rejection.

n6 Appellant argues that the "quality" clause was never activated and that all seed was accepted by the assignee. Arguments by counsel cannot take the place of factual evidence. *In re Greenfield, 571 F.2d 1185, 197 USPQ 227 (CCPA 1978).* Moreover, the assignee was never under an obligation to accept seed which was of poor quality. This lack of obligation to accept poor quality seed converted the contract into a "conditional sales" contract. [*26]

We consider next the public use aspect of the invention. As best we understand this rejection, it is the examiner's position that the use of seed by the grower, a third party, to produce and accumulate assignee's inventory of seeds, for eventual sale in the ordinary course of business, constitutes sufficient commercial activity to establish a "public use" of the claimed seed.

Appellant urges that there was no "public use" because the seed, although being produced and inventoried for sale, was not "on sale" at the time the seed was being produced. Appellant also argues that title to the seed did not pass to the grower and that the grower was heavily restricted regarding what could be done with the seed. We are unpersuaded by these arguments.

The fact situation before us is somewhat unique. The invention claimed herein was completed long prior to the filing date of the instant application (about 3 years prior). In this regard, the PVP certificate application indicates that the claimed soybean variety was developed by 1986 and that breeder seed was grown in 1987. Appellant has admitted that the use of the seed by growers was to produce and acquire seed for sale. Appellant has [*27] also admitted that the * * variety was eventually advertised, the seed was sold in the due course of business and that the amount of seed

required to supply the market is "literally millions of pounds" (Brief, pages 12, 13). The growers contract does not contain a secrecy clause.

"Public use" of a claimed invention under section 102(b) has been defined as any use of that invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor. Egbert v. Lippmann, 104 U.S. 333, 336 (1881); In re Smith, 714 F.2d 1127, 218 USPQ 976 (Fed. Cir. 1983). In the case before us the claimed seeds and plants were used by the growers to produce new plants and seeds. There is no evidence of record of a secrecy agreement between the grower and appellant. A prima facie case of public use has been made out.

The Federal Circuit recognizes four underlying policies behind the section 102(b) bar. These policies are set forth in King Instrument Corporation v. Otari Corporation, 767 F.2d 853, 226 USPQ 402 (Fed. Cir. 1985) as follows:

- (1) discouraging removal of inventions from the public domain which the public justifiably [*28] comes to believe are freely available.
 - (2) favoring prompt and widespread disclosure of inventions;
- (3) giving the inventor a reasonable amount of time following the sales activity to determine the value of a patent; and,
 - (4) prohibiting an extension of the period for exploiting the invention.

Policies (2) and (4) are applicable herein.

Even if there was an obligation of secrecy and confidentiality this does not necessarily avoid the public use bar. See T. P. Laboratories, Inc. v. Professional Positioners, Inc., 724 F.2d 965, 220 USPQ 577 (Fed. Cir. 1984). Indeed, in D. L. Auld Co. v. Chroma Graphics Corp., 714 F.2d 1144, 219 USPQ 13 (Fed. Cir. 1983), the court indicated that the statutory scheme of 35 U.S.C. § 102(b) was to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed. The public use proscription in 35 U.S.C. § 102(b) prohibits "commercial activity," i.e., the competitive exploitation of the invention by the inventor or his assigns after it is ready for patenting; the reason being that "it is part of the consideration for a patent that the public shall [*29] as soon as possible begin to enjoy the disclosure." See Metallizing Engineering Co. Inc. v. Kenyon Bearing & Auto Parts, Inc., 153 F.2d 516, 68 USPQ 54, 58 (2nd Cir. 1946).

As noted by the examiner, the grower was an independent contractor under no obligation of secrecy. The grower paid for the seed and suffered all risk of damage to a loss of the crop. Title to poor quality seed or unpurchased seed was to vest in the grower. We are of the opinion that on the facts of this case, use of the seed, by growers, with no special requirements for secrecy and confidentiality constituted commercial activity towards a competitive advantage. In this regard see *Bourne v. Jones, 114 F.Supp. 413, 98 USPQ 206 (S.D.Fla. 1951)*, wherein similar activity involving the growing of seed cane by growers was considered to be a "definite commercial use in that the growers were expanding available seed to full scale production." We recognize that the growers of *Bourne* were (a) independent of the inventor, (b) not subject to the inventor's control, (c) unaware of any restrictions at the time of their use, and (d) made use of the canes for their own purposes. Nevertheless, in this case it is [*30] "commercial activity", i.e., use of the seed by third party growers to produce large quantities of seed for eventual sale, coupled with the "on sale" aspects of the grower's contract and the apparent lack of secrecy and confidentiality requirements which constitutes the proscribed public use. We affirm the examiner's rejection.

The examiner's rejections of claims 5 through 8 under 35 U.S.C. § 112 (first paragraph) are reversed.

The examiner's rejections of claims 5 through 8 under 35 U.S.C. § 103 are affirmed.

The examiner's rejections of claims 5 through 8 under 35 U.S.C. § 102(b) (public use and on sale) are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a). See the final rule notice, 54 F.R. 29548 (July 13, 1989), 1105 O.G. 5 (August 1, 1989).

AFFIRMED

CONCURBY: GOLDSTEIN; SMITH

CONCUR:

Goldstein, Examiner-in-Chief, specially concurring:

I agree with the majority with respect to its decision of the appeal of every appealable rejection. I disagree, however, with the majority's apparent acceptance of appellant's assertion that "[t]here is no requirement that an application must be drafted in order that an examiner [*31] can formulate a search." In my opinion, there is such a requirement. It is found in the second paragraph of 35 U.S.C. 112, and a rejection under that paragraph of Section 112 would have been appropriate.

With regard to the second paragraph requirement for "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," it has been stated that the "essence of that requirement is that the language of the claims must make it clear what subject matter they encompass." In re Hammack, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970). This has been frequently stated in a shortened form as a requirement that the claims set forth the "metes and bounds" of their coverage. See, merely for example, In re Venezia, 530 F.2d 956, 958, 189 USPQ 149, 151 (CCPA 1976); In re Goffe, 526 F.2d 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); In re Watson, 517 F.2d 465, 477, 186 USPQ 11, 20 (CCPA 1975); In re Knowlton, 481 F.2d 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). This requirement has usually been viewed from the perspective of a potential infringer, "so that they may more readily and accurately determine the boundaries of [*32] protection involved and evaluate the possibility of infringement and dominance." 427 F.2d at 1382, 166 USPQ at 208. However, there is authority to support the proposition that the second paragraph requirement is also for the purpose of enabling comparison of the claimed subject matter with the prior state of the art, i.e., enabling examination.

In In re Steele, 305 F.2d 859, 134 USPQ 292 (CCPA 1962), a rejection under 35 U.S.C. 103 was formally reversed. In suggesting that the claims should "be reviewed to insure compliance with 35 U.S.C. 112," the court pointed out that, before claimed subject matter can properly be compared to the prior art, it "is essential to know what the claims do in fact cover" (emphasis supplied). The same proposition can be found to be at least strongly implicit in the decisions in In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971), and In re Merat, 519 F.2d 1390, 186 USPQ 471 (CCPA 1975). The decision in the former case stated that, if upon analysis the claims were found to be indefinite under the second paragraph of 35 U.S.C. 112, they could not even be analyzed under the first paragraph of 35 U.S.C. 112, because that analysis of [*33] the claims could not be carried out unless one was able "to determine exactly what subject matter they encompass[ed]." This reasoning would clearly apply equally well to an analysis of the claims with regard to the prior state of the art. In the latter case, the court stated that its affirmance of the 35 U.S.C. 112, second paragraph, rejection rendered it "unnecessary to discuss the other grounds of rejection," which included a rejection under 35 U.S.C. 103 based on the prior state of the art. Of course, the portion of the concurring opinion in Argoudelis quoted in footnote 3 of the majority opinion here, albeit it is from a concurring opinion, is at least further evidence that the proposition set forth here is correct.

In the event of further prosecution of this subject matter before the examiner, I firmly recommend that a rejection be made under the second paragraph of 35 U.S.C. 112 on the basis of the issue raised by the examiner in objecting to the specification, i.e., that the claims read in light of the specification could not be examined with regard to the prior state of the art. When the issue has been raised under the proper paragraph of Section 112, it may be more [*34] readily developed and, in the event of a subsequent appeal, more appropriately briefed.

John D. Smith, Examiner-in-Chief, concurring:

The majority affirms the examiner's "on sale" rejection of the appealed claims under 35 U.S.C. § 102(b) in part on the grounds that at all times during performance of the contract there was a distinct possibility that title could change hands. Although I concur with the result reached by the majority with respect to this rejection, I am aware of no legal precedent, nor have appellants or the majority cited any, which holds that a patent defeating "sale" under 35 U.S.C. § 102(b) requires a transfer of title of the property.

A "sale" has been broadly defined as a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay to the seller for the thing bought or sold, 77 C.J.S. Sales § 1 (1952), and this broad definition has been applied to a "sale" as defined by 35 U.S.C. § 102(b). In re Caveney, 761 F.2d 671, 226 USPQ 1 (Fed. Cir. 1985). Here, the contract requires the grower to purchase seed from applicant's assignee in exchange for a valuable property right, the right to use [*35] the seed by planting it for the purpose of producing a new plant which produces more seed. Although the grower cannot use any rejected seed for planting purposes, the implied right to plow under the new plant produced to fertilize the grower's acreage is itself a valuable "right of property." Moreover, as noted by the majority, the grower has the right to use rejected seed for purposes other

than planting. Thus, in my view, any purchasing of seed by a grower constitutes an actual "sale" under 35 U.S.C. § 102(b).

With the exception noted above, I agree with the majority with respect to its decision of the appeal and its reasoning regarding all other rejections.